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Fallin et al.

EXTENSION

ROD CONTOURING APPARATUS FOR PERCUTANEOUS PEDICLE SCREW

(71) Applicant: Stryker European Holdings I, LLC,

Kalamazoo, MI (US)

(72) Inventors: T. Wade Fallin, Logan, UT (US);

Joshua A. Butters, Chandler, AZ (US)

(73) Assignee: Stryker European Holdings I, LLC,

Kalamazoo, MI (US)

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CPC *A61B 90/06* (2016.02); *A61B 17/0218* (2013.01); *A61B 17/7002* (2013.01);

(Continued)

(58) Field of Classification Search

CPC . A61B 17/70; A61B 17/7002; A61B 17/7011; A61B 17/7013

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(56)

U.S. PATENT DOCUMENTS

References Cited

3,788,318 A 1/1974 Kim et al. 3,789,852 A 2/1974 Kim et al. (Continued)

FOREIGN PATENT DOCUMENTS

DE 3711091 10/1988 DE 4238339 A1 5/1994 (Continued)

OTHER PUBLICATIONS

European Search Report for Application No. EP17160251 dated Jun. 7, 2017.

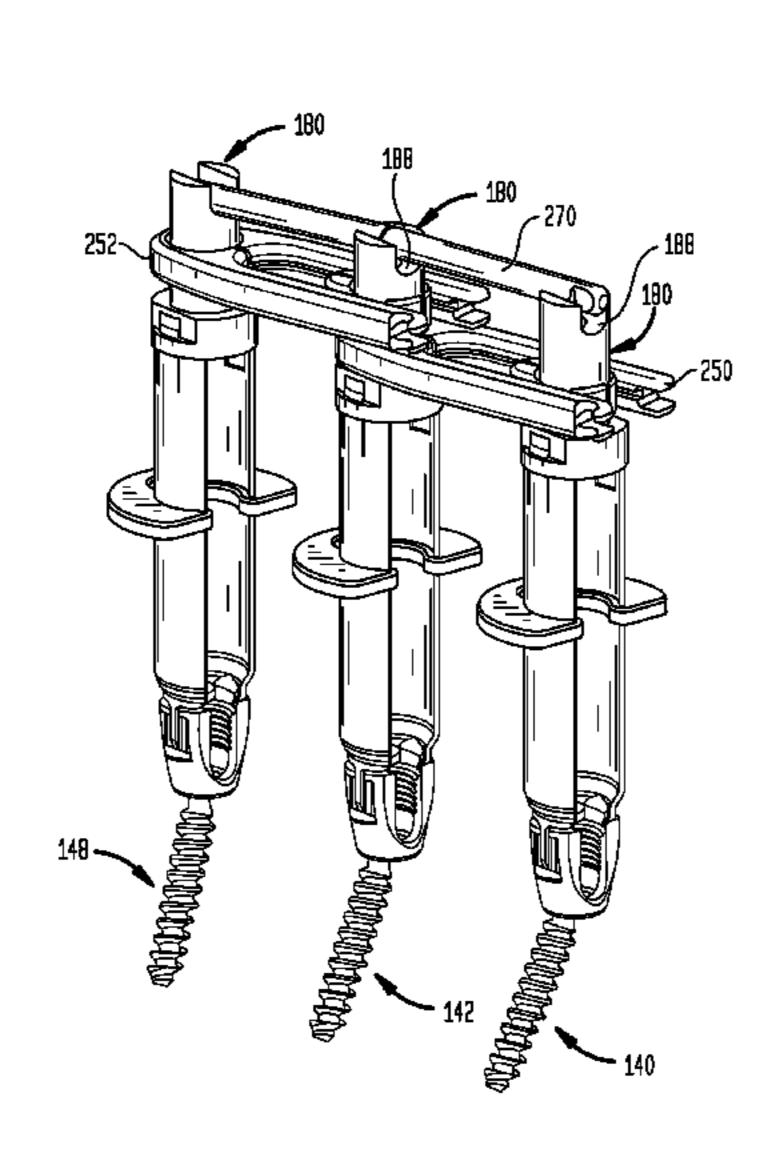
(Continued)

Primary Examiner — Matthew Lawson (74) Attorney, Agent, or Firm — Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) ABSTRACT

Anatomic points within the body are projected outside the body through the use of extenders (180, 182, 188). The projected points may then be used for measurement, or to facilitate the selection or configuration of an implant that is positioned proximate the anatomic points using a slotted cannula (143). Such an implant may be a rod (270) for a posterior spinal fusion system. Pedicle screws (140, 142, 148) may be implanted into pedicles of the spine, and may then serve as anchors for the extenders. The extenders (180, 182, 188) may have rod interfaces (214, 216, 218) that receive the rod (270) in a manner that mimics the geometry of the pedicle screws (140, 142, 148) so that the selected or configured contoured rod (270) will properly fit into engagement with the pedicle screws (140, 142, 148).

17 Claims, 19 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/316,637, filed on Dec. 15, 2008, now Pat. No. 9,247,977, which is a division of application No. 11/526,785, filed on Sep. 25, 2006, now Pat. No. 8,894,655.

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- (52) **U.S. Cl.**CPC *A61B 17/7032* (2013.01); *A61B 17/7041*(2013.01); *A61B 17/7085* (2013.01); *A61B 17/88* (2013.01); *A61B 17/8863* (2013.01); *A61B 17/7037* (2013.01); *A61B 17/8897*(2013.01); *A61B 2090/061* (2016.02)

(56) References Cited

U.S. PATENT DOCUMENTS

2 002 222 4	7/1075	NT C 1 1
3,892,232 A		Neufeld
4,083,370 A		
4,350,151 A	9/1982	Scott
4,409,968 A	10/1983	Drummond
4,411,259 A	10/1983	Drummond
4,448,191 A	5/1984	Rodnyansky et al.
4,449,532 A	5/1984	
4,474,046 A	10/1984	Cook
4,545,374 A		Jacobson
4,611,581 A		Steffee
4,653,481 A		Howland et al.
4,790,297 A		
4,817,587 A	4/1989	-
4,862,891 A	9/1989	
• •		
4,887,595 A		Heinig et al.
4,899,729 A		Gill et al.
4,913,134 A		-
4,957,495 A		•
5,010,879 A		Moriya et al.
· · · · · · · · · · · · · · · · · · ·		Engelhardt et al.
5,125,396 A	6/1992	Ray
5,171,279 A	12/1992	Mathews
5,183,464 A	2/1993	Dubrul et al.
5,195,541 A	3/1993	Obenchain
5,242,443 A	9/1993	Kambin
5,295,994 A		Bonutti
D346,217 S	4/1994	Sparker et al.
5,357,983 A		-
5,360,431 A		
5,373,860 A		
5,395,317 A		Kambin
5,409,488 A		
5,425,732 A		
5,439,464 A		Shapiro
5,480,440 A		Kambin
·		
5,490,409 A		
5,496,322 A		Mathews
5,545,228 A		Kambin
5,569,248 A		Mathews
5,569,290 A		McAfee
5,584,887 A	12/1996	Kambin
5,591,165 A	1/1997	Jackson
5,601,590 A	2/1997	Bonutti et al.
5,624,442 A	4/1997	Mellinger et al.
5,658,286 A	8/1997	Sava
5,720,751 A		Jackson
5,728,097 A		Mathews
5,741,261 A		Moskowitz et al.
-, <u>.,</u> 11	1000	THE TELEVISION OF THE

5 746 720 A	5/1009	Standar Ir
5,746,720 A 5,762,629 A	5/1998 6/1998	Stouder, Jr. Kambin
5,702,029 A 5,792,044 A	8/1998	Foley et al.
5,792,044 A 5,814,046 A	9/1998	Hopf et al.
5,882,344 A	3/1999	Stouder, Jr.
5,885,291 A	3/1999	Moskovitz et al.
5,885,292 A	3/1999	Moskovitz et al.
5,891,147 A	4/1999	Moskovitz et al.
5,902,231 A	5/1999	Foley et al.
RE36,221 E	6/1999	Breard et al.
5,928,139 A	7/1999	Koros et al.
5,938,662 A	8/1999	Rinner
5,944,658 A	8/1999	Koros et al.
5,954,635 A	9/1999	Foley et al.
5,957,888 A	9/1999	Hinchliffe
5,961,499 A	10/1999	Bonutti et al.
5,964,761 A	10/1999	Kambin
5,976,146 A	11/1999	Ogawa et al.
6,007,487 A	12/1999	Foley et al.
6,015,409 A	1/2000	Jackson
6,033,406 A	3/2000	Mathews
6,035,691 A	3/2000	Lin et al.
6,090,113 A	7/2000	Le Couedic et al
6,123,707 A	9/2000	Wagner
6,127,597 A 6,152,871 A	10/2000 11/2000	Beyar et al.
6,159,179 A	12/2000	Foley et al. Simonson
6,162,170 A	12/2000	Foley et al.
6,175,758 B1	1/2001	Kambin
6,183,472 B1	2/2001	Lutz
6,187,000 B1	2/2001	Davison et al.
6,197,002 B1	3/2001	Peterson
6,200,322 B1	3/2001	Branch et al.
6,206,822 B1	3/2001	Foley et al.
6,206,826 B1	3/2001	Mathews et al.
6,217,509 B1	4/2001	Foley et al.
6,226,548 B1	5/2001	Foley et al.
6,235,028 B1	5/2001	Brumfield et al.
6,287,313 B1	9/2001	Sasso
6,332,780 B1	12/2001	Traxel et al.
6,371,968 B1	4/2002	Kogasaka et al.
6,425,859 B1	7/2002	Foley et al.
6,485,518 B1	11/2002	Cornwall et al.
6,506,151 B2 6,520,907 B1	1/2003 2/2003	Estes et al.
6,524,320 B2	2/2003	Foley et al. DiPoto
6,530,926 B1	3/2003	Davison
6,530,929 B1	3/2003	Justis et al.
6,562,046 B2	5/2003	Sasso
6,575,979 B1	6/2003	Cragg
6,596,008 B1	7/2003	Kambin
6,605,095 B2	8/2003	Grossman
6,607,530 B1	8/2003	Carl et al.
6,723,095 B2	4/2004	Hammerslag
6,740,089 B2	5/2004	Haider
6,749,614 B2	6/2004	Teitelbaum et al
6,770,074 B2	8/2004	Michelson
6,793,656 B1	9/2004	Mathews
6,800,084 B2	10/2004	Davison et al.
6,811,558 B2	11/2004	Davison et al.
6,821,277 B2 6,837,891 B2	11/2004 1/2005	Teitelbaum Davison et al.
6,849,064 B2	2/2005	Hamada
6,875,212 B2	4/2005	Shaolian et al.
6,899,713 B2	5/2005	Shaolian et al.
6,923,811 B1	8/2005	Carl et al.
6,929,647 B2	8/2005	Cohen
6,964,667 B2	11/2005	Shaolian et al.
7,008,422 B2	3/2006	Foley et al.
7,008,424 B2	3/2006	Teitelbaum
7,011,660 B2	3/2006	Sherman et al.
7,083,621 B2	8/2006	Shaolian et al.
7,160,300 B2	1/2007	Jackson
7,188,626 B2	3/2007	Foley et al.
7,250,052 B2	7/2007	Landry et al.
7,282,064 B2	10/2007	Chin
7,306,603 B2		Boehm, Jr. et al.
7,758,617 B2		Iott et al.
7 811 288 B2		

7,811,288 B2 10/2010 Jones et al.

US 10,070,936 B2 Page 3

(56)	Referer	ices Cited		70917 A1	3/2005	
U.S	S. PATENT	DOCUMENTS	2005/00	80418 A1 85813 A1 90822 A1	4/2005	Simonson et al. Spitler et al. DiPoto
7,927,360 B2	4/2011	Pond, Jr. et al.		90822 A1		DiPoto
7,955,355 B2				13833 A1	5/2005	Davison
8,002,798 B2		Chin et al.		24991 A1	6/2005	
8,177,817 B2		_		31407 A1 31408 A1		Sicvol et al. Sicvol et al.
8,192,440 B2 RE45,338 E		Jones et al. Chin et al.		31421 A1		Anderson et al.
RE45,676 E		Chin et al.		31422 A1		Anderson et al.
2001/0011170 A1		Davison et al.		37461 A1 37593 A1		Marchek et al. Gray et al.
2001/0027320 A1 2001/0029353 A1		Sasso Peterson		49022 A1		Shaolian et al.
2001/0029393 A1 2001/0049498 A1		Davison et al.		49035 A1		Pimenta et al.
2001/0049527 A1		~~		54389 A1 71540 A1		Selover et al. Lim et al.
2001/0053915 A1 2002/0016583 A1		Grossman Cragg		82410 A1		Jackson
2002/0010383 A1 2002/0045904 A1		Fuss et al.		92570 A1		Jackson
2002/0068975 A1		Teitelbaum et al.		45928 A1		Colleran et al.
2002/0082598 A1		Teitelbaum		51139 A1 77934 A1	11/2005 12/2005	Kon Vardiman
2002/0082600 A1 2002/0107519 A1		Shaolian et al. Dixon et al.				Kullas A61F 2/0063
2002/0107919 711 2002/0116006 A1		Cohen				606/99
2002/0161367 A1				30839 A1		Park et al. Simonson et al.
2002/0161368 A1 2002/0173796 A1		Foley et al.		30858 A1 30861 A1		Simonson et al. Simonson et al.
2002/01/3/30 A1 2002/0198526 A1		Shaolian et al.		11713 A1		Jackson
2003/0060824 A1	3/2003	Viart et al.		11714 A1	5/2006	
2003/0060826 A1		Foley et al.		00135 A1 17735 A1		Sherman et al. MacDonald et al.
2003/0073998 A1 2003/0083688 A1		Pagliuca et al. Simonson				Iott A61B 17/701
2003/0139648 A1		Foley et al.				606/86 A
2003/0195518 A1		~~	2006/02	47658 A1*	* 11/2006	Pond, Jr A61B 17/7082
2003/0199872 A1 2003/0199884 A1		Markworth et al. Davison et al.	2006/02/	64934 A1	11/2006	606/104 Fallin
2003/019989 A1				64962 A1	11/2006	
2003/0208202 A1	11/2003	Falahee		93680 A1	12/2006	
2003/0225408 A1		Nichols et al.		43359 A1		Altarac et al.
2003/0229353 A1 2004/0006341 A1		Shaolian et al.		83210 A1 93824 A1*		Hestad et al. Hestad A61B 17/7032
2004/0006344 A1		Nguyen et al.				606/261
2004/0034351 A1		Sherman et al.	2007/019	91840 A1*	8/2007	Pond, Jr A61B 17/7037
2004/0039384 A1 2004/0059333 A1		Boehm et al. Carl et al.	2008/00	09864 A1	1/2008	623/17.16 Forton et al.
2004/0082954 A1		Teitelbaum et al.		16328 A1		Birkmeyer et al.
2004/0082960 A1		Davison		28056 A1		Jackson
2004/0082961 A1 2004/0087950 A1		Teitelbaum Teitelbaum		37915 A1		Anderson et al.
2004/0092934 A1		Howland		31901 A1		Iott et al.
2004/0093001 A1		Hamada		15678 A1 77692 A1	1/2011 3/2011	Jackson Jackson
2004/0106934 A1 2004/0133201 A1		Grossman Shluzas et al.		52940 A1		Frigg et al.
2004/0133201 A1 2004/0138662 A1		Landry et al.	2011/02	38120 A1	9/2011	Chin
2004/0143265 A1	7/2004	Landry et al.		45884 A9		Brumfield et al.
2004/0143268 A1		Falahee		89191 A1 23477 A1		Altarac et al. Landry et al.
2004/0147928 A1 2004/0147936 A1		Landry et al. Rosenberg et al.		58070 A1		Jackson
2004/0172022 A1	9/2004	Landry et al.	2012/019	97302 A1	8/2012	Fallin
2004/0176763 A1		Foley et al.			~1.T.D.I.D.D.	
2004/0194791 A1 2004/0215190 A1		Sterman et al. Nguyen et al.		FOREI	GN PATE	NT DOCUMENTS
2004/0215193 A1		Shaolian et al.	DE	297	10979 U1	8/1997
2004/0236317 A1		Davison	DE		26754 A1	2/1999
2004/0254576 A1 2004/0260287 A1		Dunbar et al. Ferree	DE		27988	1/2002
2004/0267279 A1		Casutt et al.	DE DE		09073 U1 07495 U1	8/2004 8/2005
2005/0010220 A1		Casutt et al.	EP		28177	2/1993
2005/0010221 A1 2005/0021030 A1		Dalton Pagliuca et al.	EP	06	11116	8/1994
2005/0021030 A1 2005/0021031 A1		Foley et al.	EP EP		65731 06888	8/1995 6/2000
2005/0033297 A1	2/2005	Davison	EP EP		74786	1/2004
2005/0038432 A1		Shaolian et al.	EP	140	68652	10/2004
2005/0038434 A1 2005/0043741 A1		Mathews Michelson	EP		45355	6/2005
2005/0043741 A1 2005/0043742 A1		Bruneau et al.	JP JP		11190 A 04505 A	3/2003 2/2006
2005/0059969 A1	3/2005	McKinley	SU		39513	6/1981
2005/0065515 A1		Jahng	WO		18722	9/1993
2005/0065517 A1	3/2005	Cnin	WO	940	09726	5/1994

(56)	References Cited			
	FOREIGN PATENT DOCUMENTS			
WO	9514437 6/1995			
WO	97/14457 4/1997			
WO	9822030 A1 5/1998			
WO	98/36785 8/1998			
WO	00/45720 8/2000			
WO	01/012080 2/2001			
WO	01/037744 5/2001			
WO	0141681 A1 6/2001			
WO	01/060234 8/2001			
WO	01/060263 8/2001			
WO	01/060270 8/2001			
WO	01/095823 12/2001			
WO	03020110 3/2003			
WO	03028566 4/2003			
WO	03/037170 5/2003			
WO	03/057055 7/2003			
WO	03/079914 10/2003			
WO	03/088810 10/2003			
WO	03/088878 10/2003			
WO	04004584 1/2004			
WO	04017847 3/2004			
WO	04021899 3/2004			
WO	04/028382 4/2004			
WO	04/037070 5/2004			
WO	04037074 5/2004			
WO	04041100 5/2004			
WO	2004058045 7/2004			
WO	04080318 A1 9/2004			
WO	05018466 3/2005			
WO	05023123 3/2005			
WO	05032358 4/2005			
WO	05060534 A 7/2005			
WO	05072081 8/2005			
WO	06/125029 11/2006			
WO	06116662 11/2006			
🔾	11,200			

OTHER PUBLICATIONS

Leu et al., Percutaneous Fusion of the Lumbar Spine, State of the Art Reviews, vol. 6, No. 3, pp. 593-604, Sep. 1992.

Kambin, Arthroscopic Lumbar Intervertebral Fusion, Chapter 95, The Adult Spine, vol. 2, pp. 2037-2046, Jan. 1997.

Kambin et al., Anterior Column Support for Failed Fusion, Revision Spine Surgery, pp. 589-600, published Jan. 1999.

Kambin, The Role of Minimally Invasive Surgery in Spinal Disorders, Advance Operative Orthopedics, vol. 3, pp. 147-171, Dec. 1994.

Kambin, "Arthroscopic Microdiscectomy", The Journal of Arthroscopy, vol. 8, No. 3, pp. 287-295, Sep. 1992.

Kambin et al, "Percutaneous Posterolateral Lumbar Discectomy and Decompression with a 6.9-millimeter cannula", The Journal of Bone and Joint Surgery, pp. 822-831, Jul. 1991.

Kambin, "Arthroscopic Microdiskectomy", The Mount Sinai Journal of Medicine, vol. 58, No. 2, Mar. 1991, pp. 159-164.

Kambin, "Posterolateral Percutaneous suction-excision of herniated lumbar intervertebral discs", Clinical Orthopaedics and Related Research. No. 207, pp. 37-42, Jun. 1988.

Kambin, Posterolateral Percutaneous Lumbar Interbody Fusion, Arthroscopic Microdiscectomy, pp. 117-121, Jan. 1991.

Kambin, Posterolateral Percutaneous Lumbar Discectomy and Decompression Arthroscopic Microdiscectomy, Section IV. pp. 67-100, Jan. 1991.

Spinal Concepts; Access Dilation Port, Spinal Concepts Web Page information 2 pages, downloaded Mar. 16, 2005, http://www.spinalconcepts.com/products/adp.html.

Sofamor Danek; Sextant CD Horizon Sextant Rod Insertion System, Surgical Technique, Techniques, p. 1-29, 2003.

Sofamor Danek; Metrx, X-Tube, Refraction System; Sofamor Danek Web page information p. 1-2, printed Mar. 29, 2005.

Sofamor Danek; Eclipse CD Horizon Eclipse Implants and Instruments, Information from the Sofamor Danek Web page, p. 1-3, printed Mar. 29, 2005.

Smith and Nephew; 6.5mm and 4.0mm Cannulated Screws, Surgical Technique, p. 1-24, 1998.

Pathfinder; Minimally Invasive Pedicie Fixation System. Spinal Concepts Product Brochure p. 1-4, May 2003.

Diapason, Surgical Texchnique Catalog, Diapasan Spinal System, Jan. 2002.

Maxcess; XLIF 90° Surgical Technique. Nuvasive Creative Spine Technology Product Brochure, p. 1-26, 2005.

Office Action from U.S. Appl. No. 11/178,035, dated Mar. 4, 2009.

Office Action from U.S. Appl. No. 11/178,035, dated Sep. 5, 2008. Office Action from U.S. Appl. No. 11/178,035, dated May 1, 2008.

Office Action from U.S. Appl. No. 11/1/8,033, dated May 1, 2008. Office Action from U.S. Appl. No. 11/202,487, dated Dec. 9, 2008.

Office Action from U.S. Appl. No. 10/868,075, dated Mar. 9, 2009.

Office Action from U.S. Appl. No. 10/868,075, dated Mar. 24, 2008. Office Action from U.S. Appl. No. 10/868,075, dated Oct. 12, 2007.

U.S. Appl. No. 11/202,487, filed Aug. 12, 2005. U.S. Appl. No. 10/868,075, filed Jun. 15, 2004.

U.S. Appl. No. 11/178,035, filed Jul. 8, 2005.

Office Action from U.S. Appl. No. 11/178,035, dated Nov. 13, 2009.

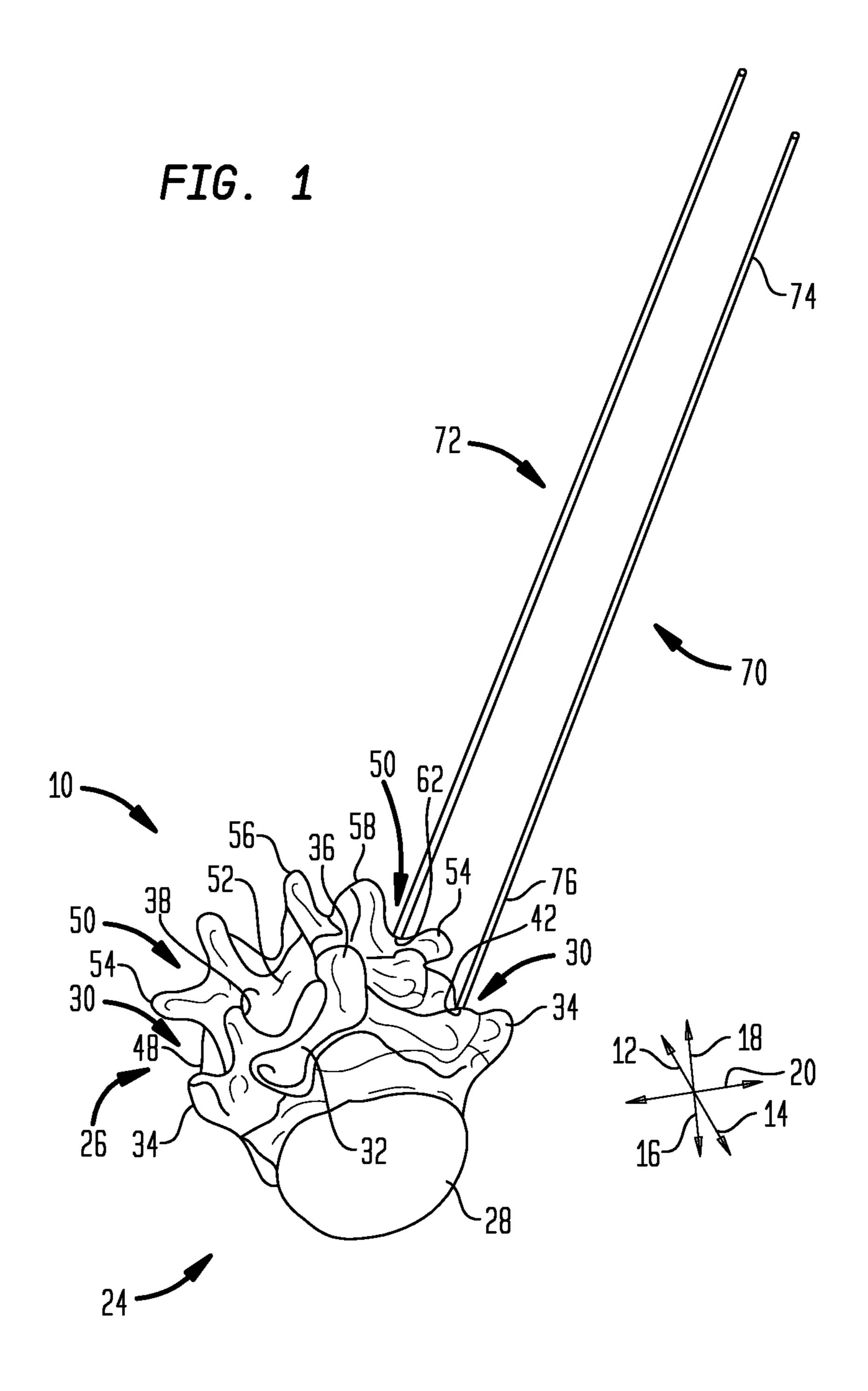
Office Action from U.S. Appl. No. 11/202,487, dated Aug. 5, 2009. U.S. Appl. No. 11/904,029, filed Sep. 25, 2007.

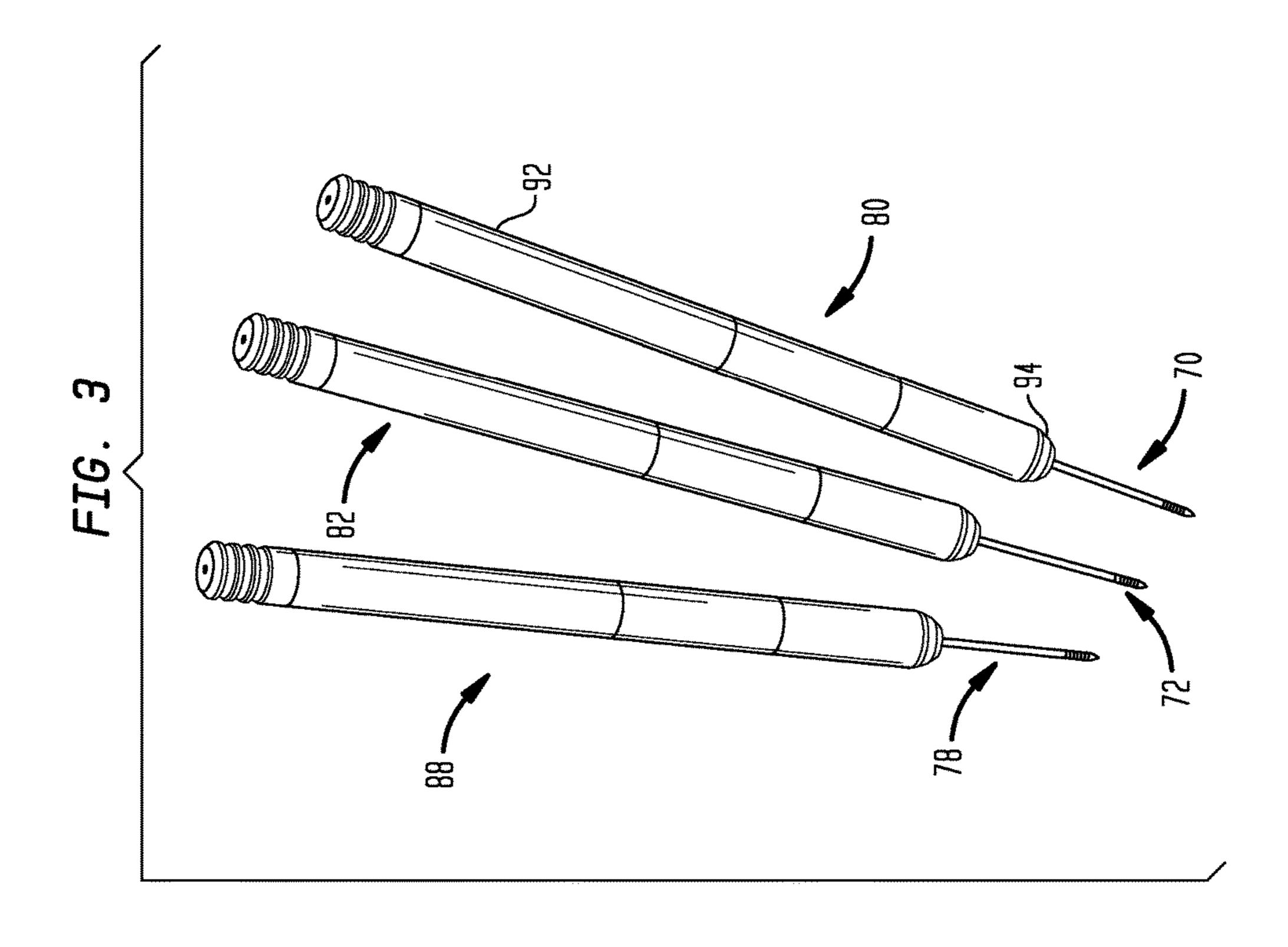
U.S. Appl. No. 11/904,030, filed Sep. 25, 2007.

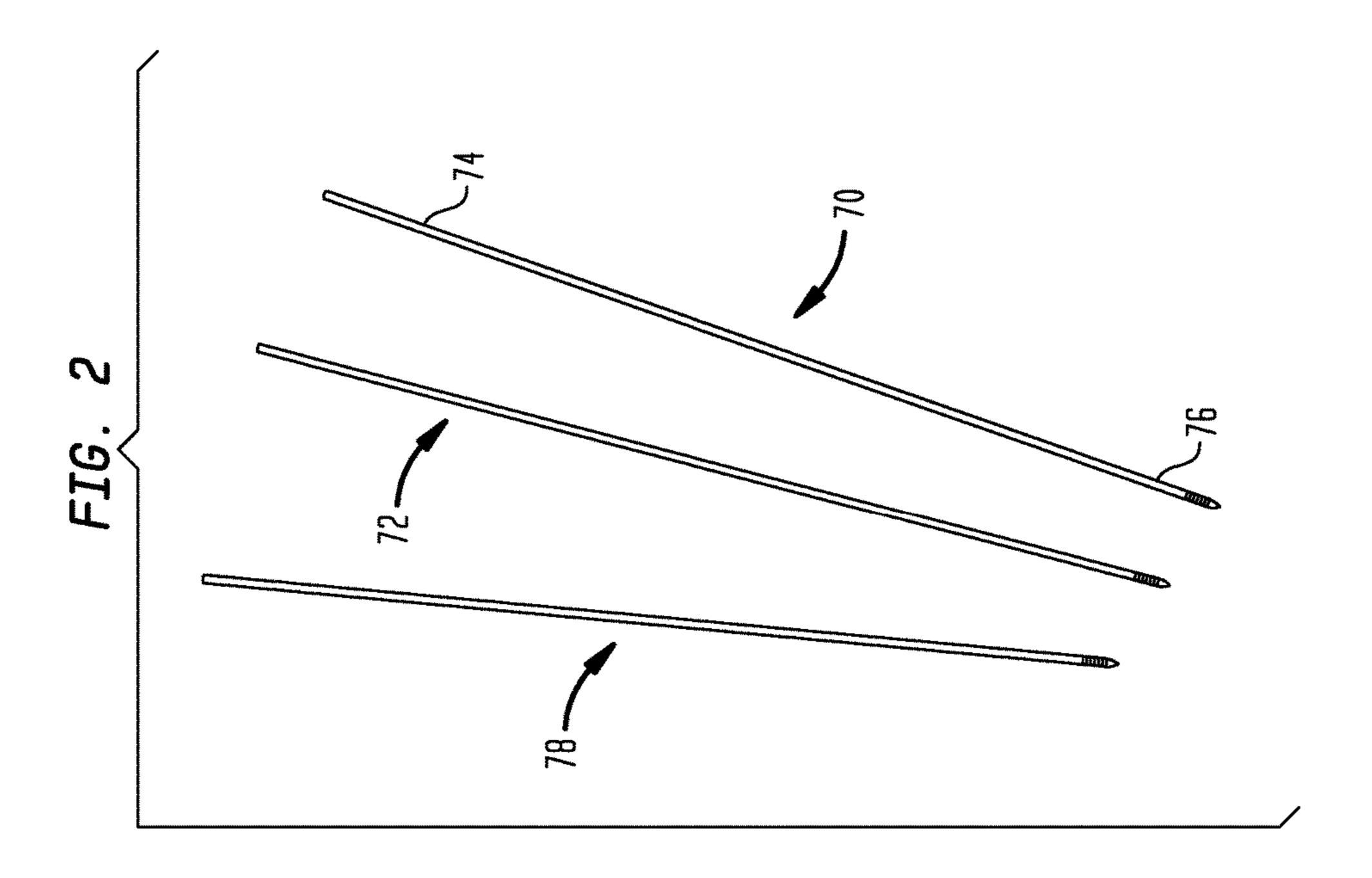
Office Action from U.S. Appl. No. 12/316,637, dated Oct. 17, 2011. Office Action from Japanese Application No. 2008-55422 dated Sep. 2, 2011.

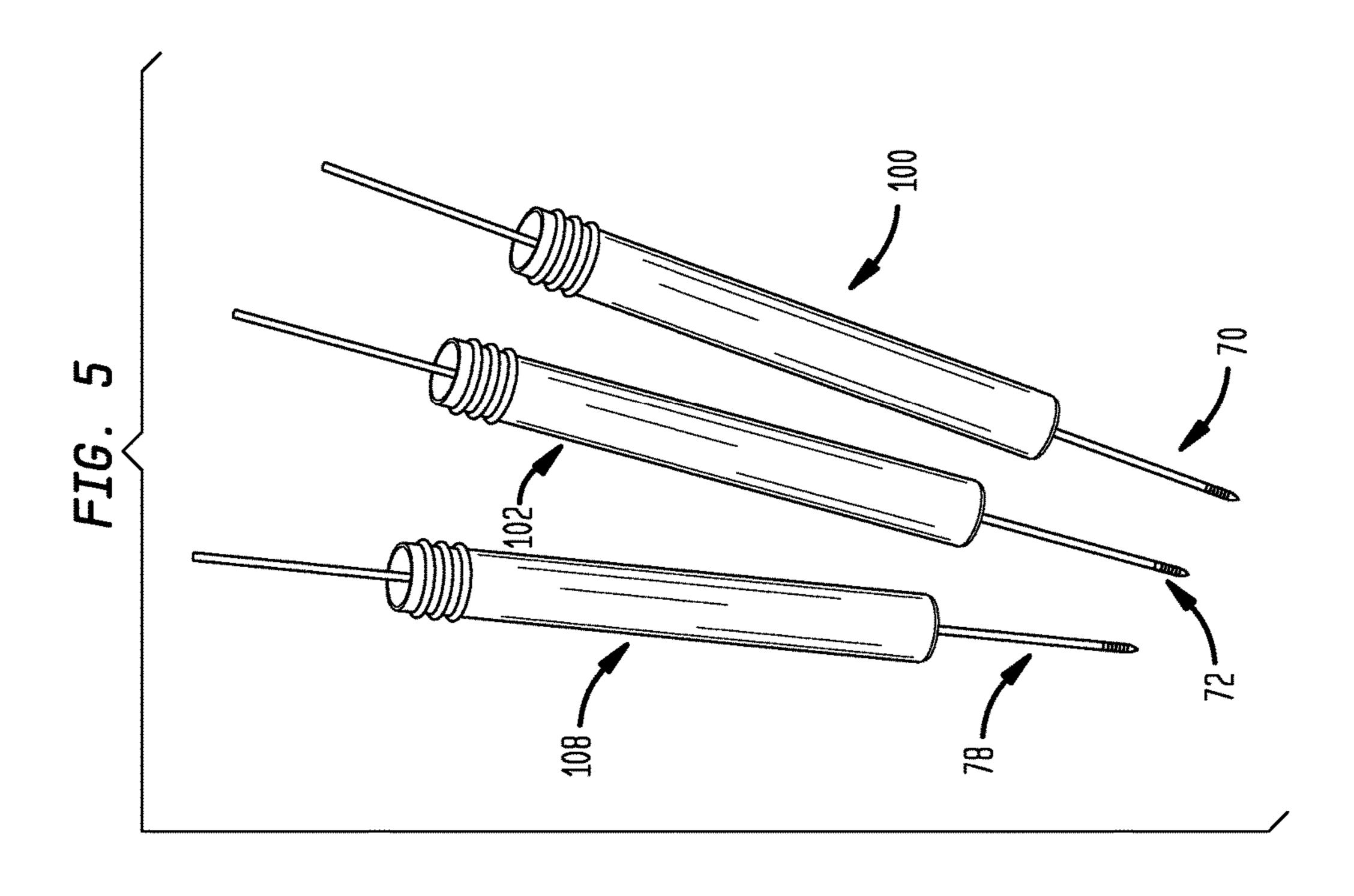
Kambin, Minimally Invasive Techniques in Spinal Surgery Current Practice, Neurosurgical Focus, www.spineuniversecom, 16 pages, printed Aug. 24, 2005.

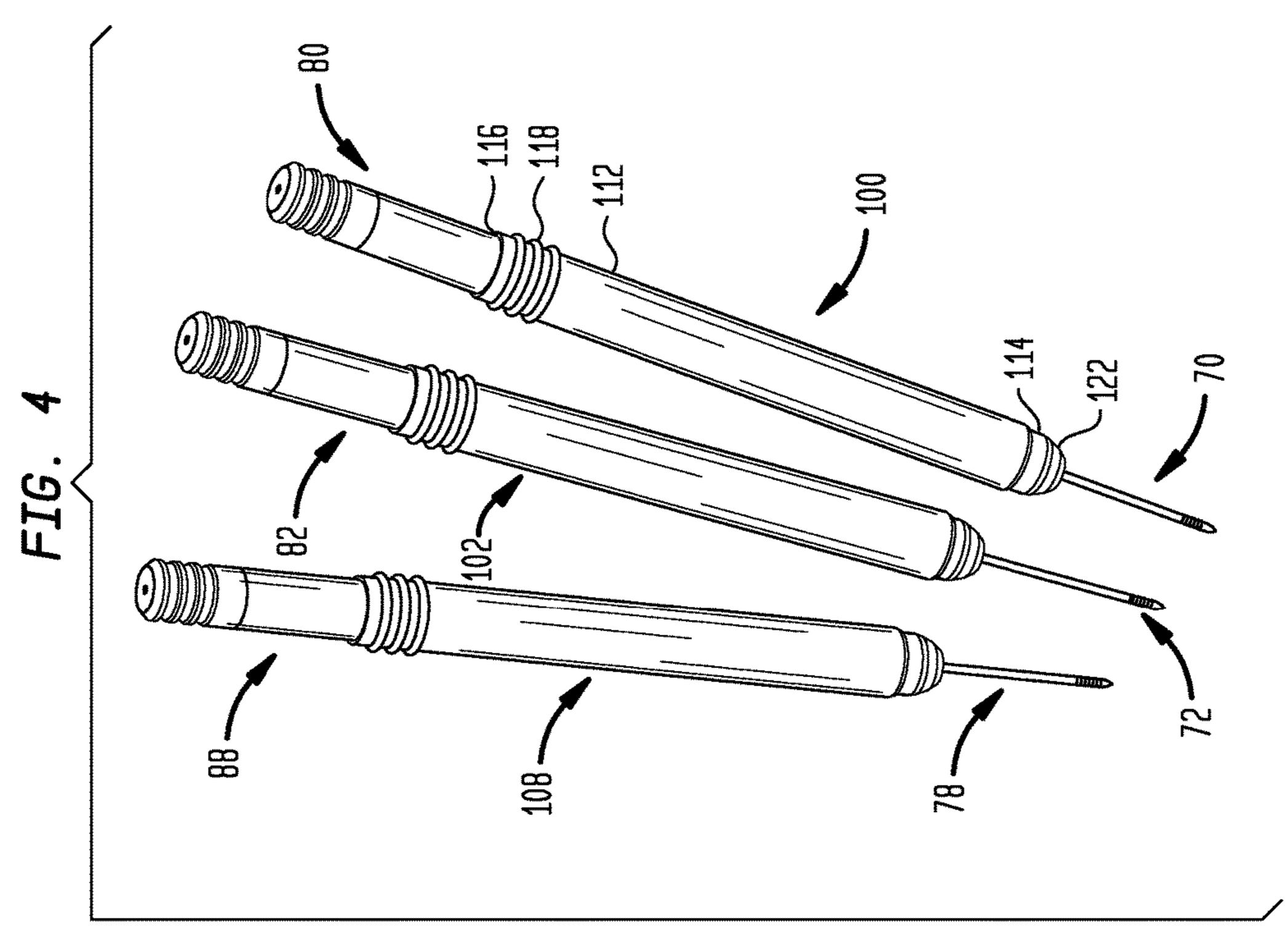
^{*} cited by examiner

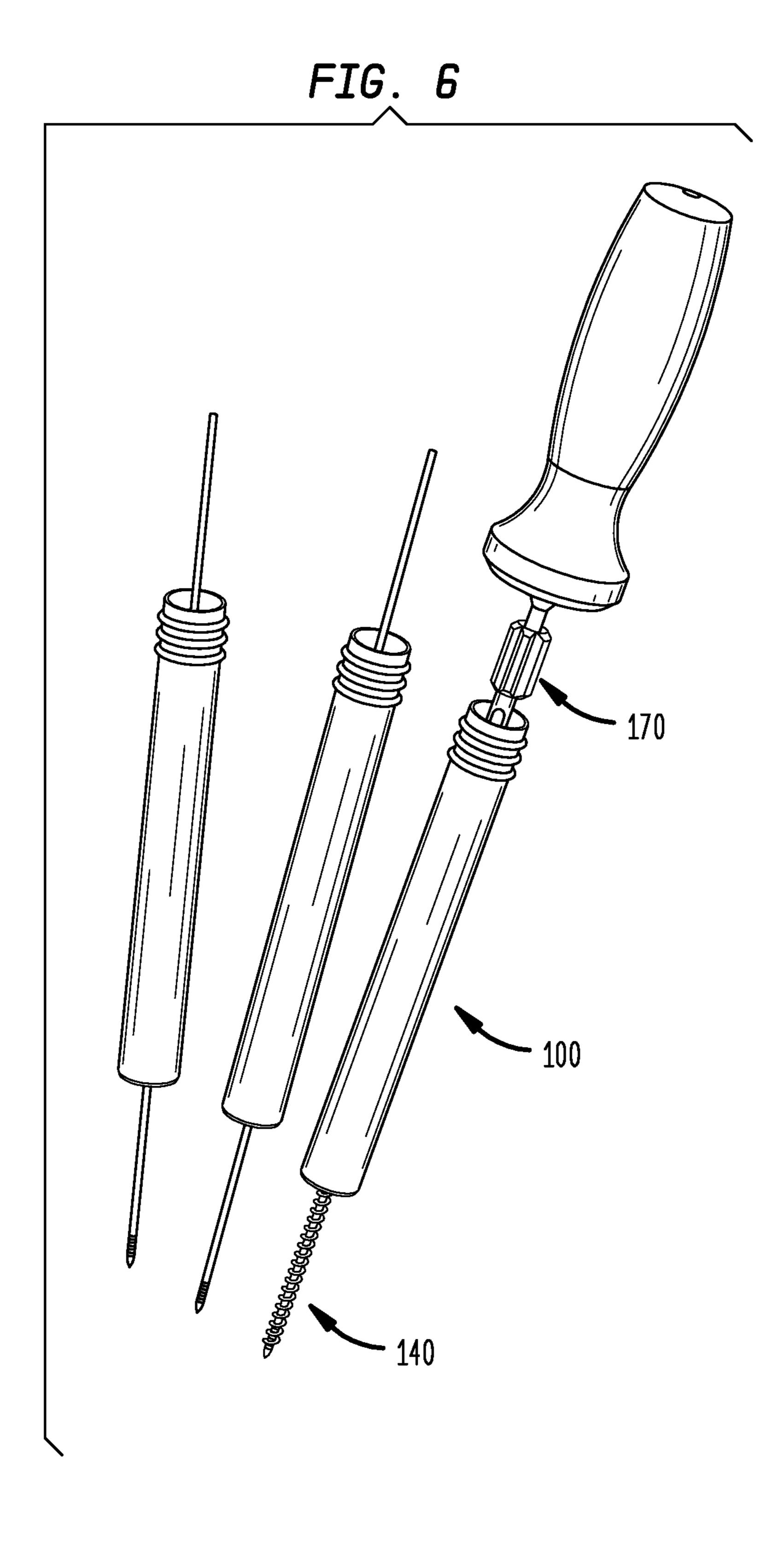


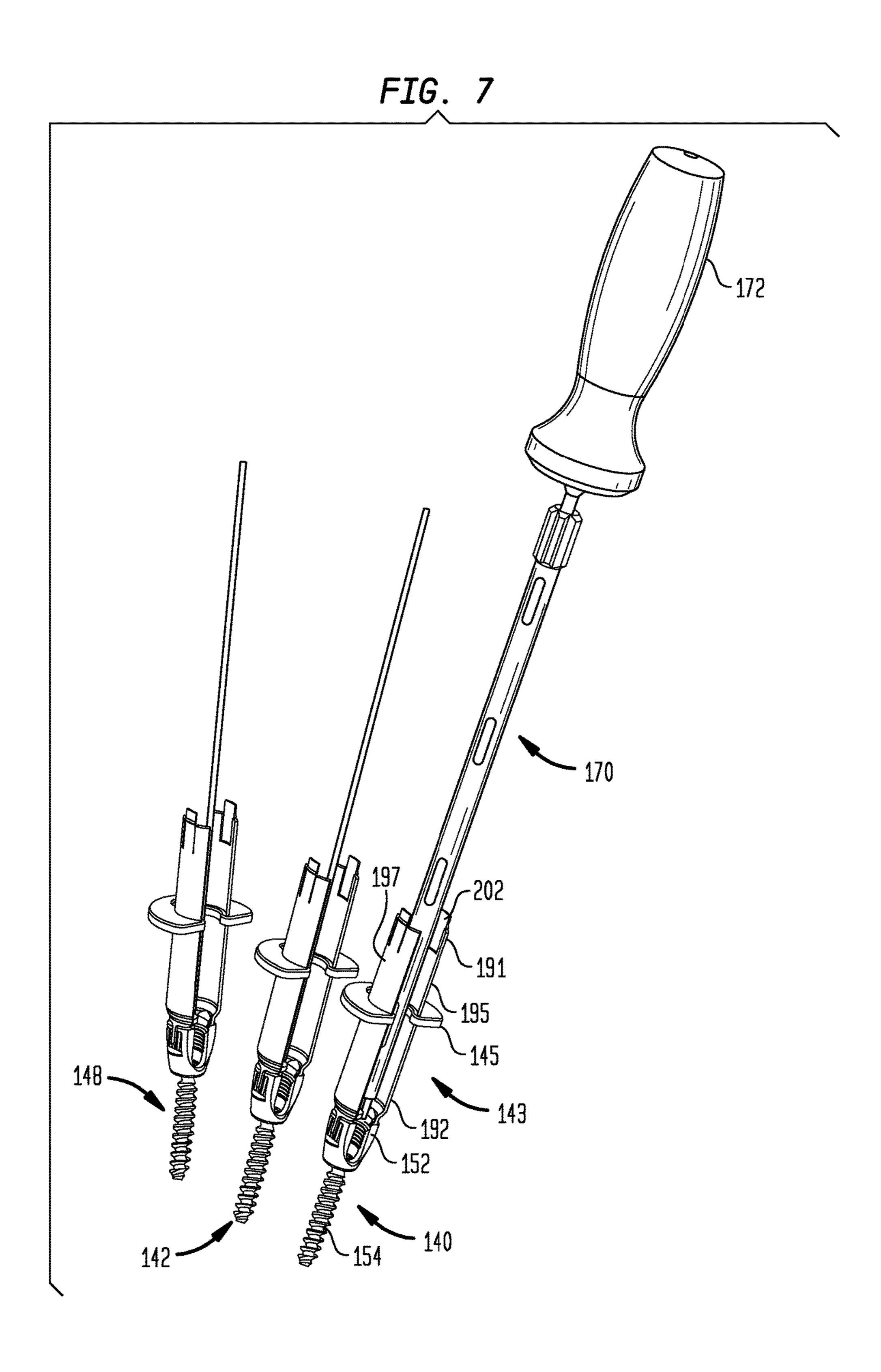


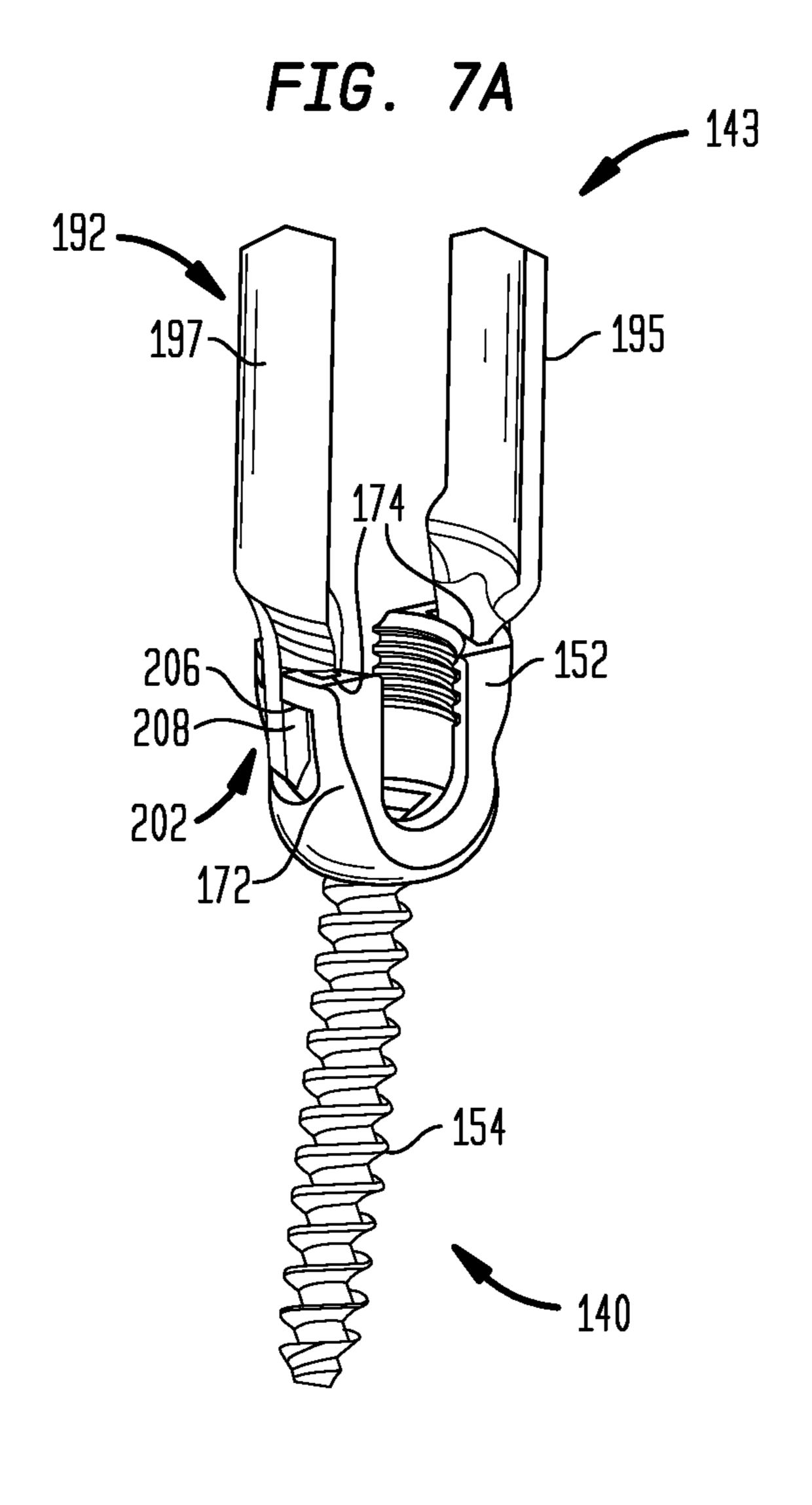


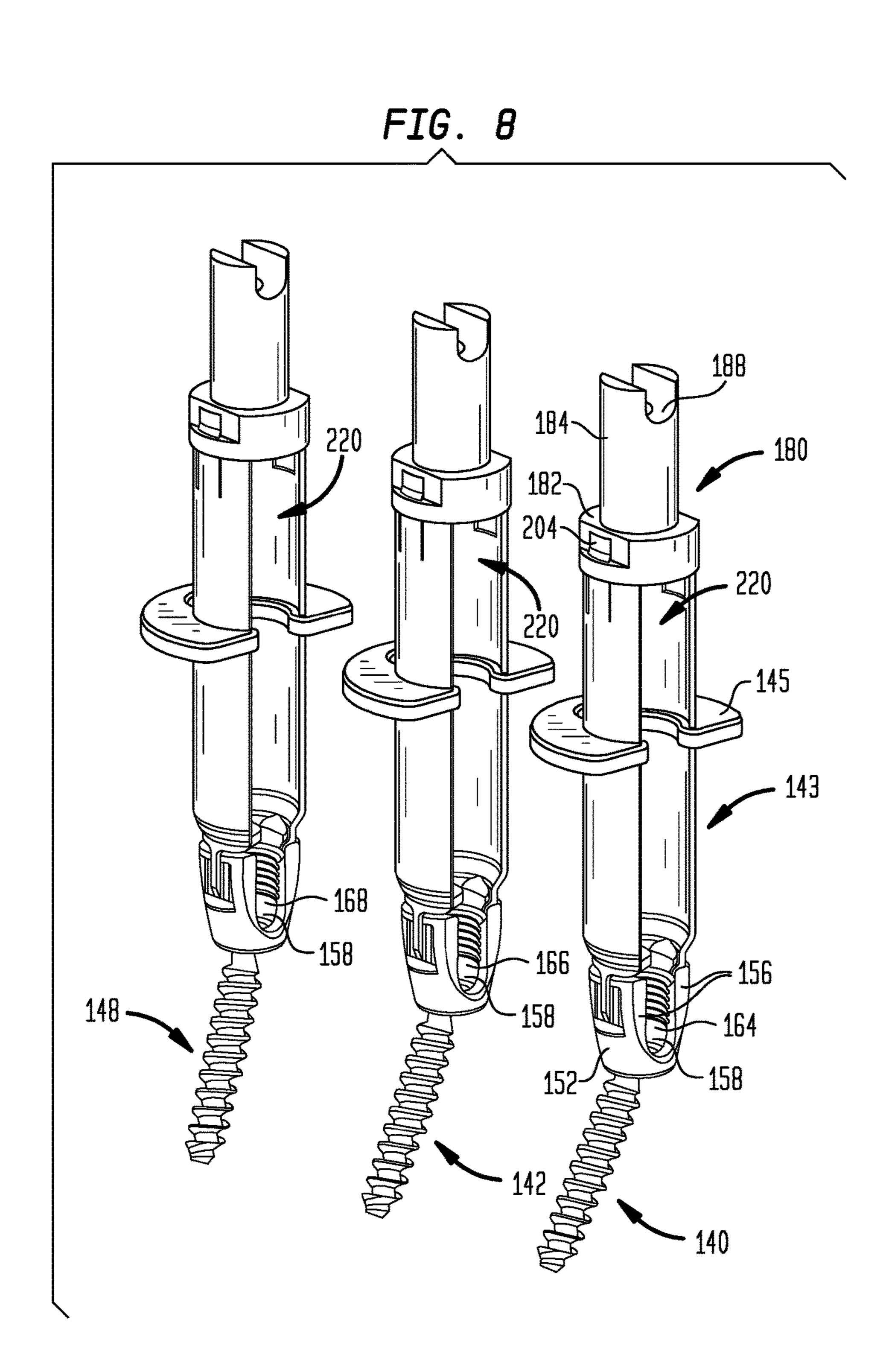


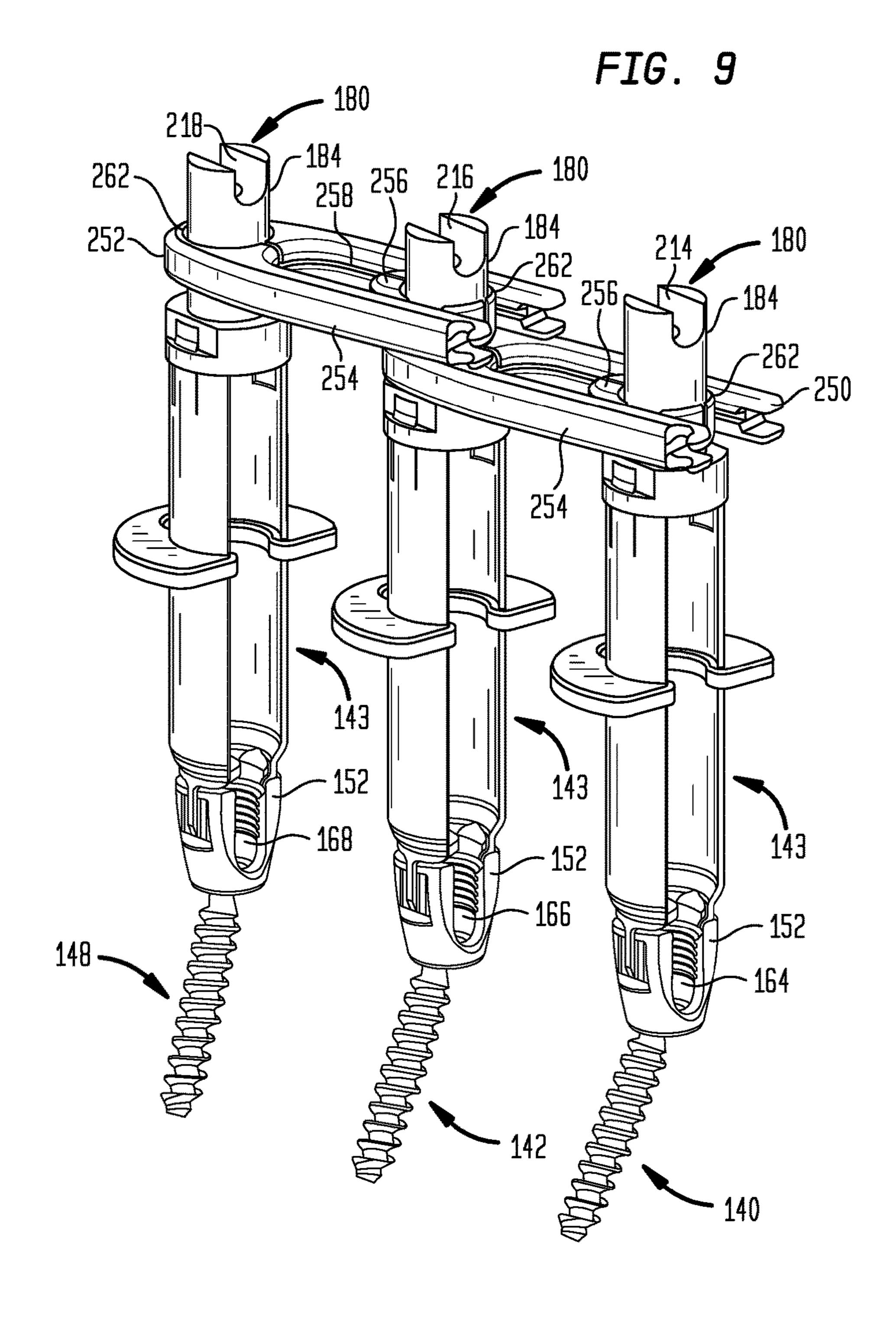


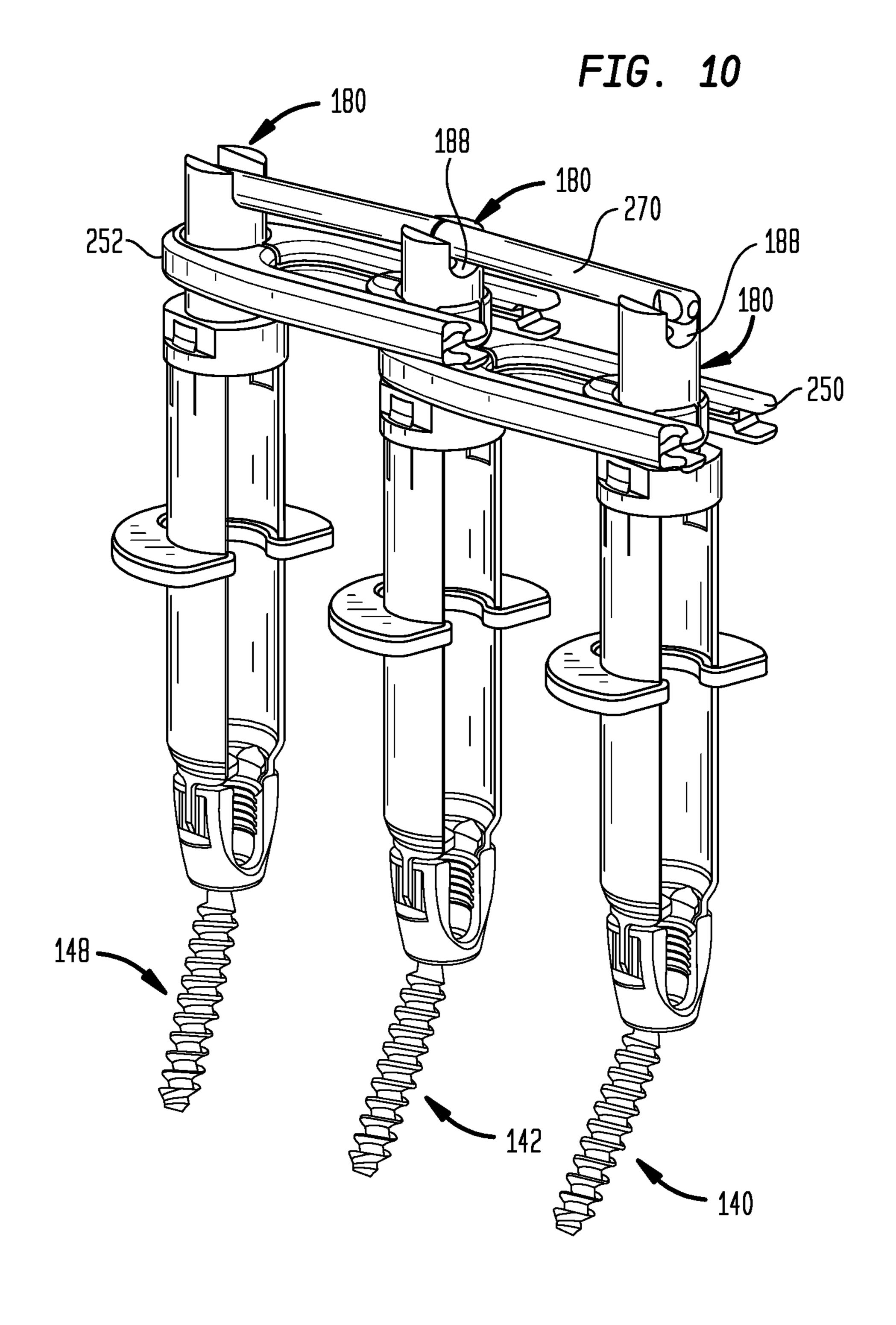


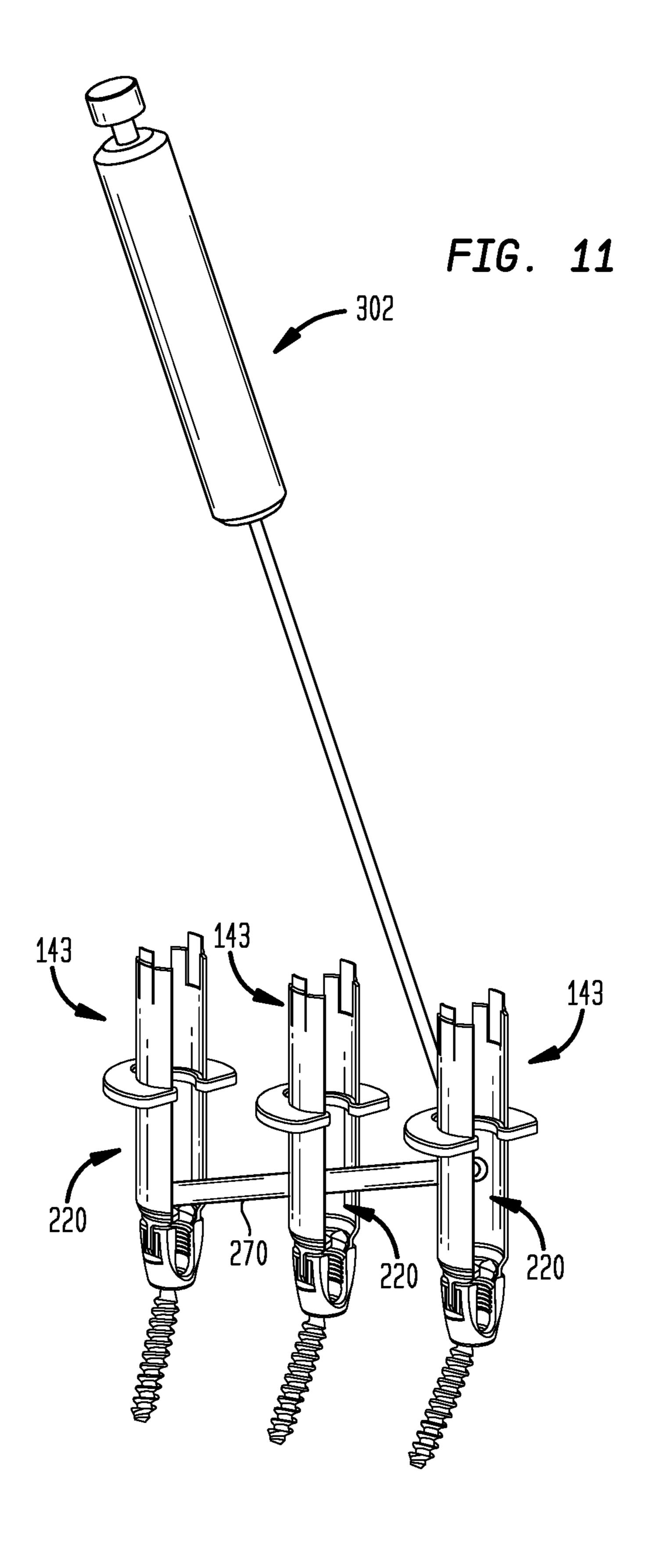












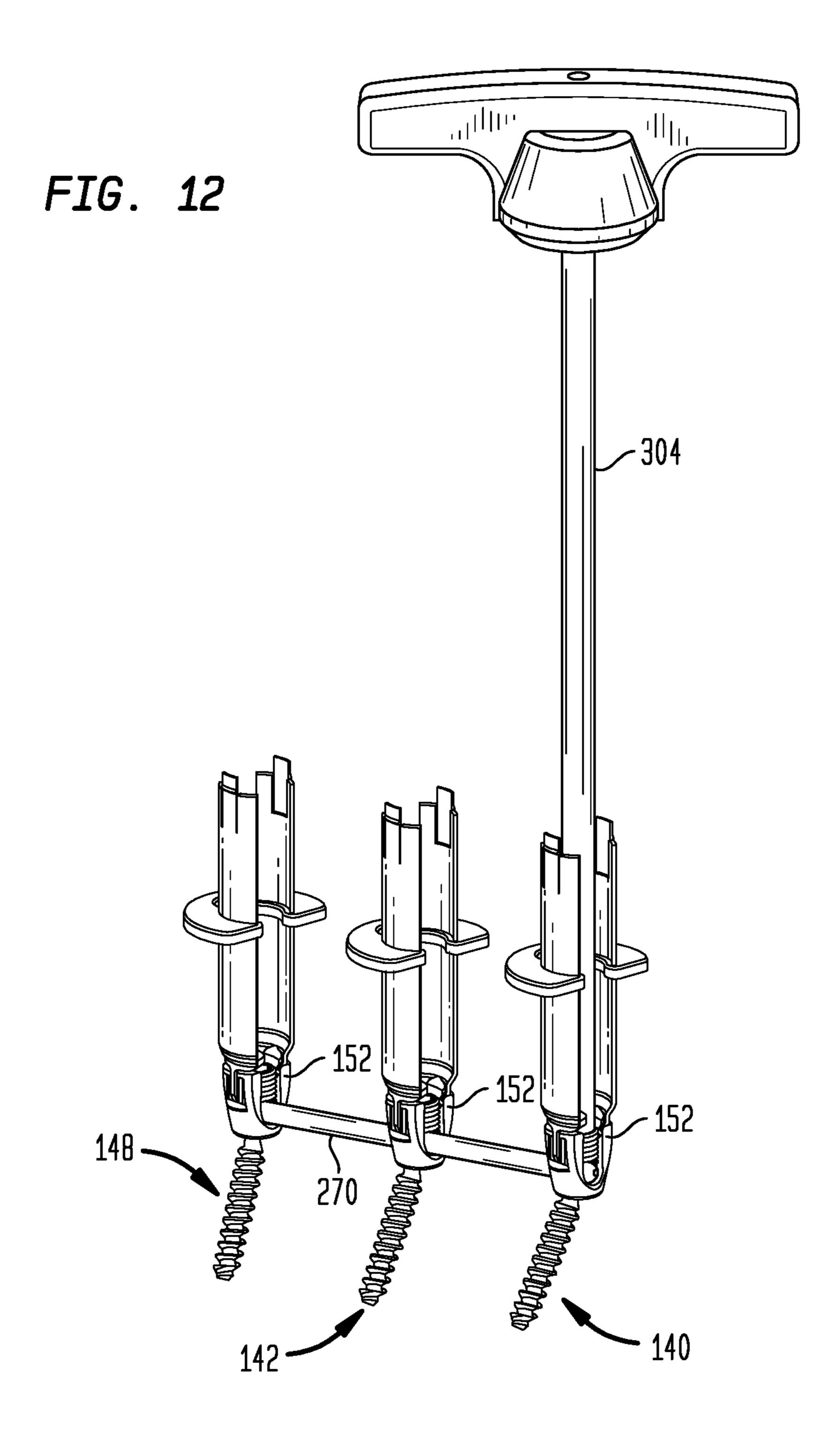


FIG. 13

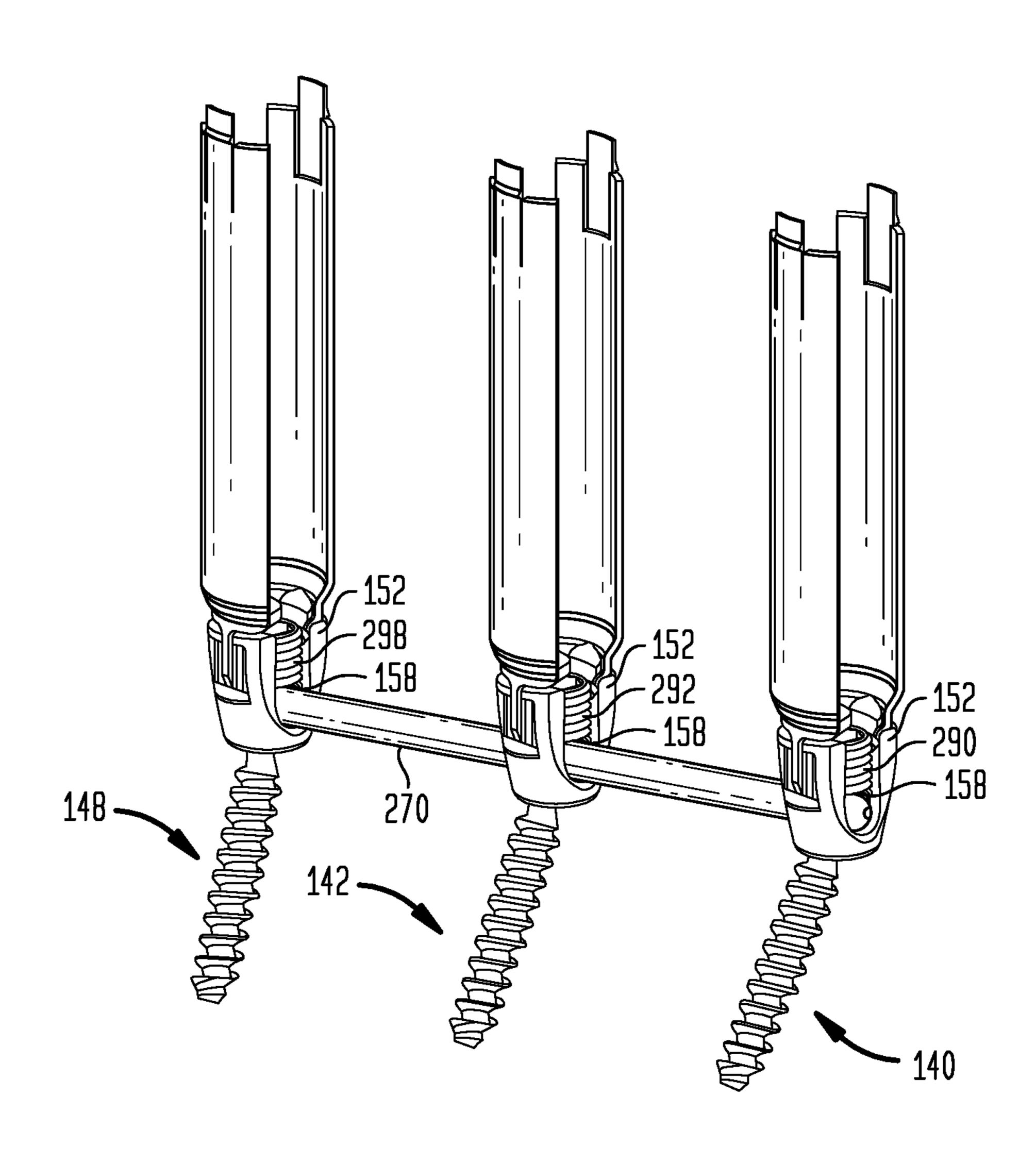
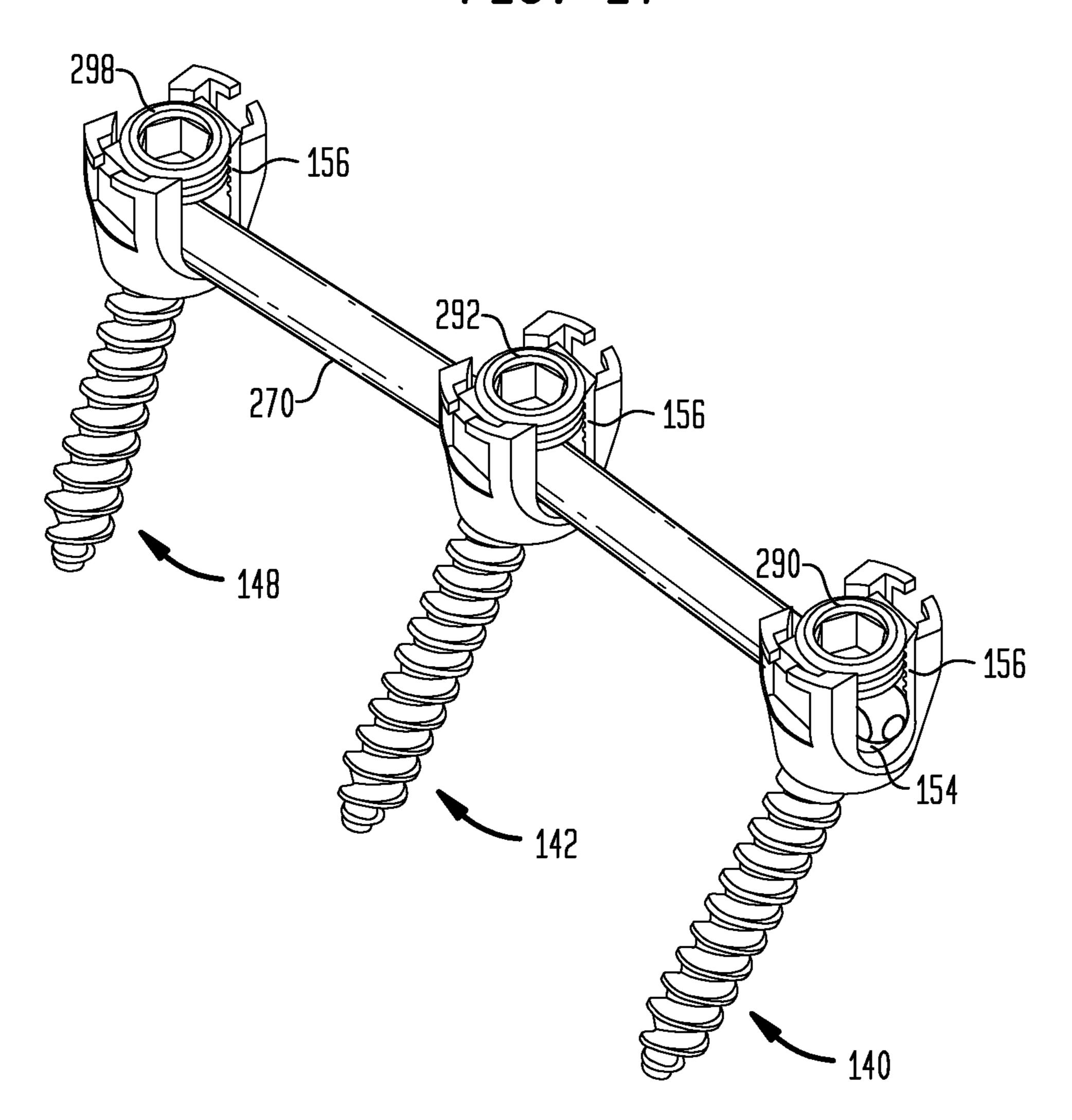
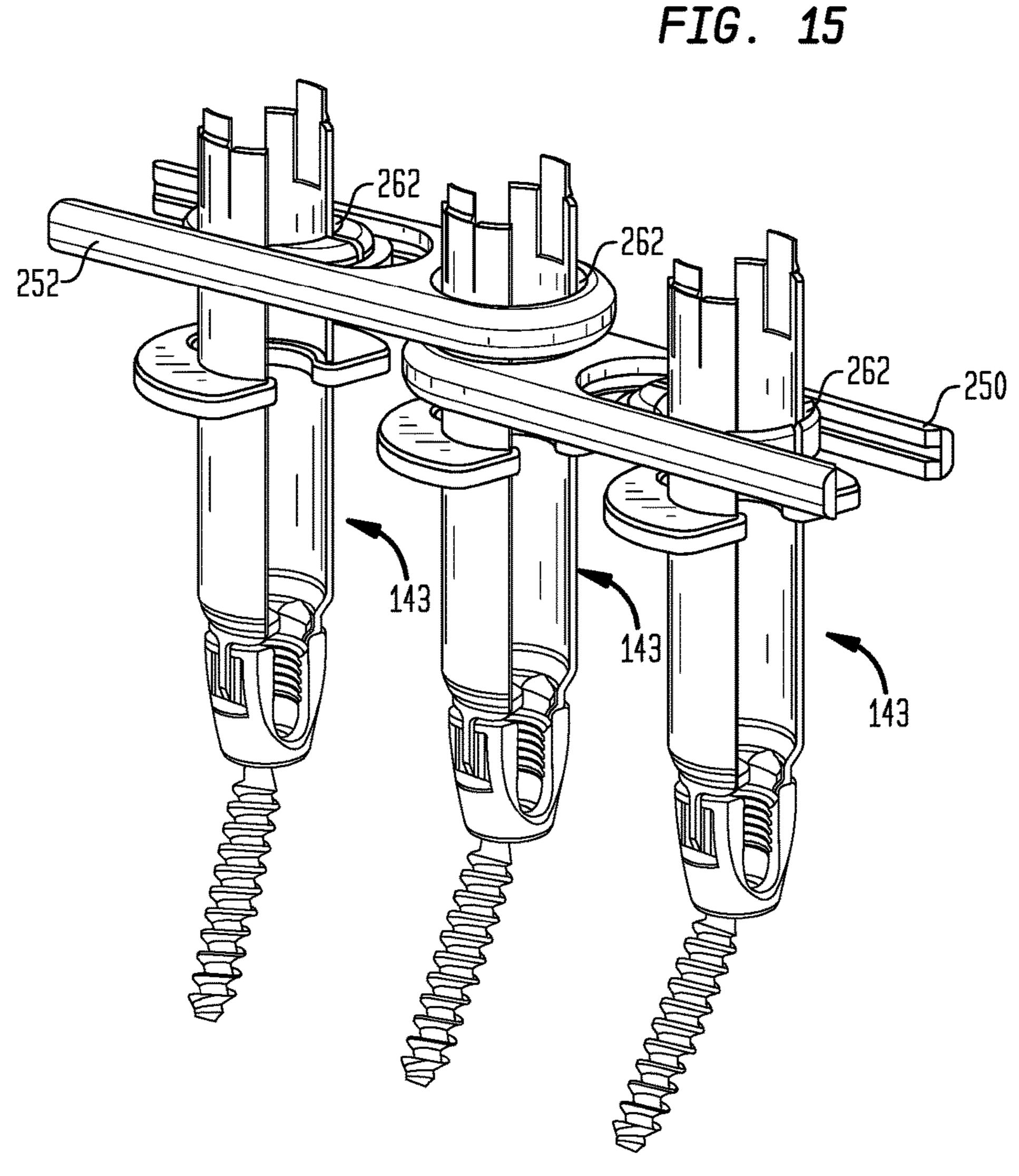
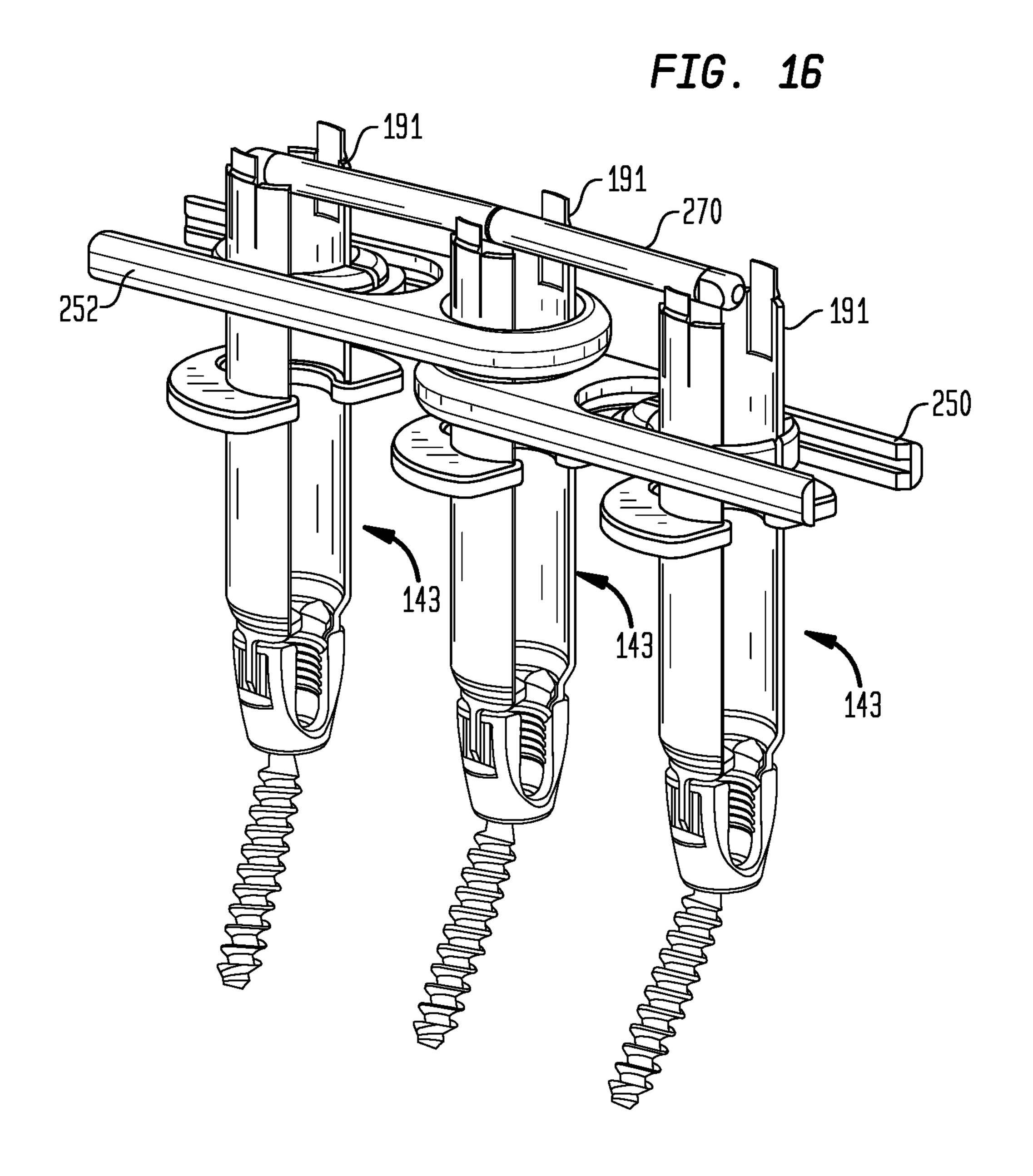
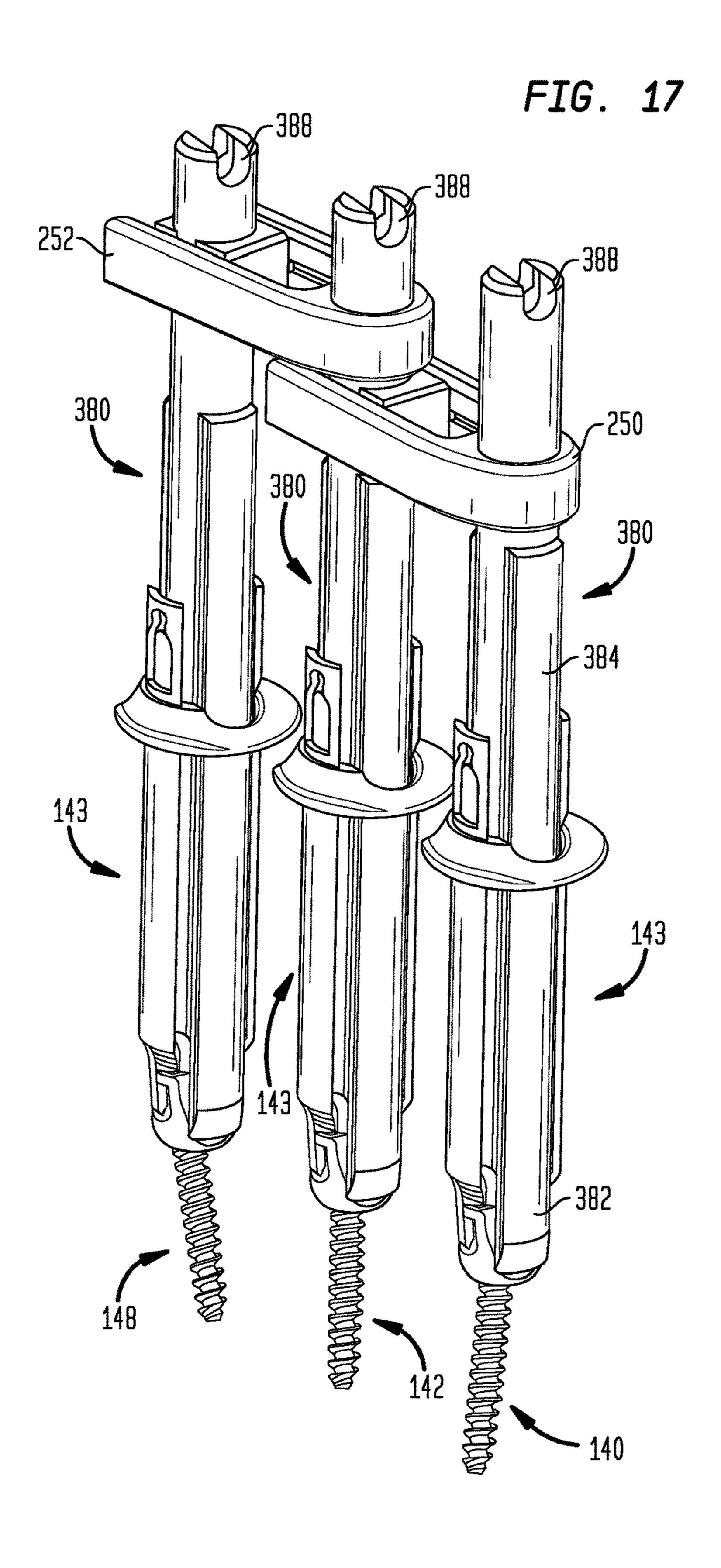


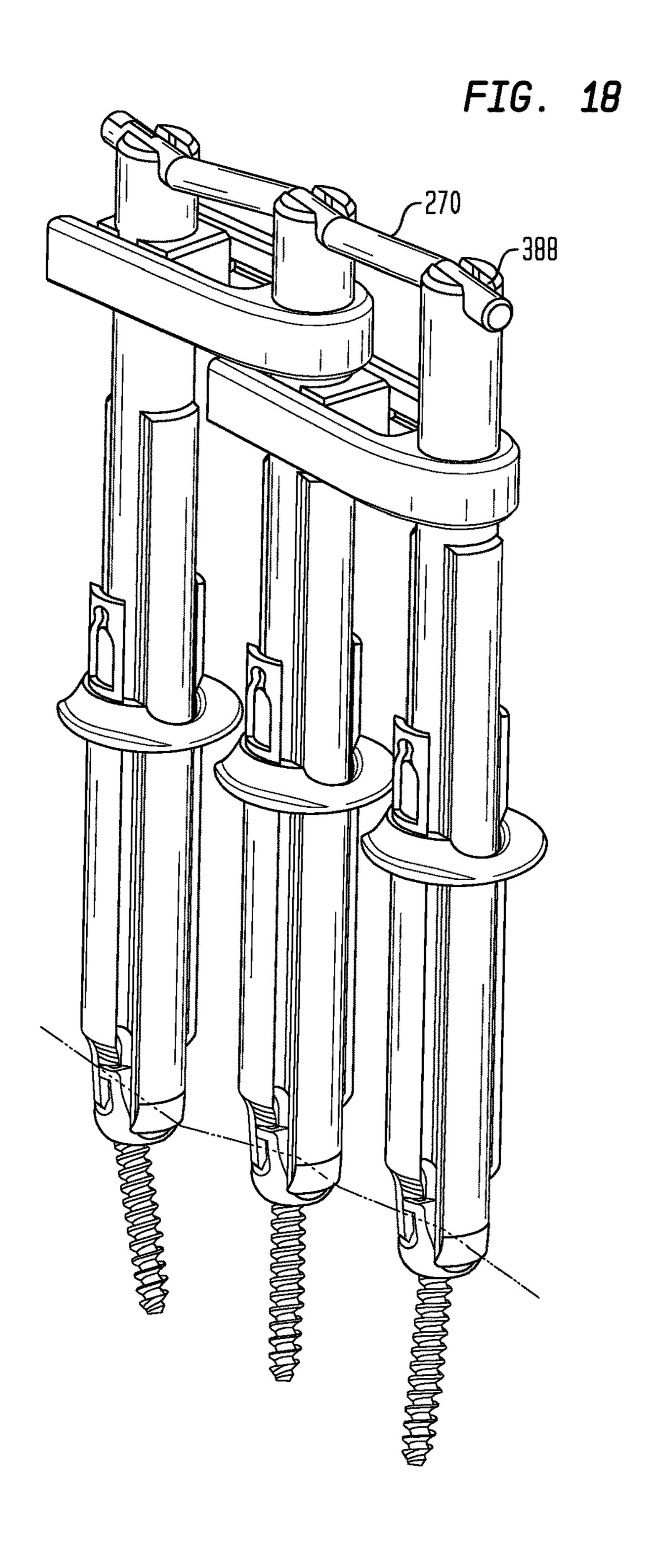
FIG. 14

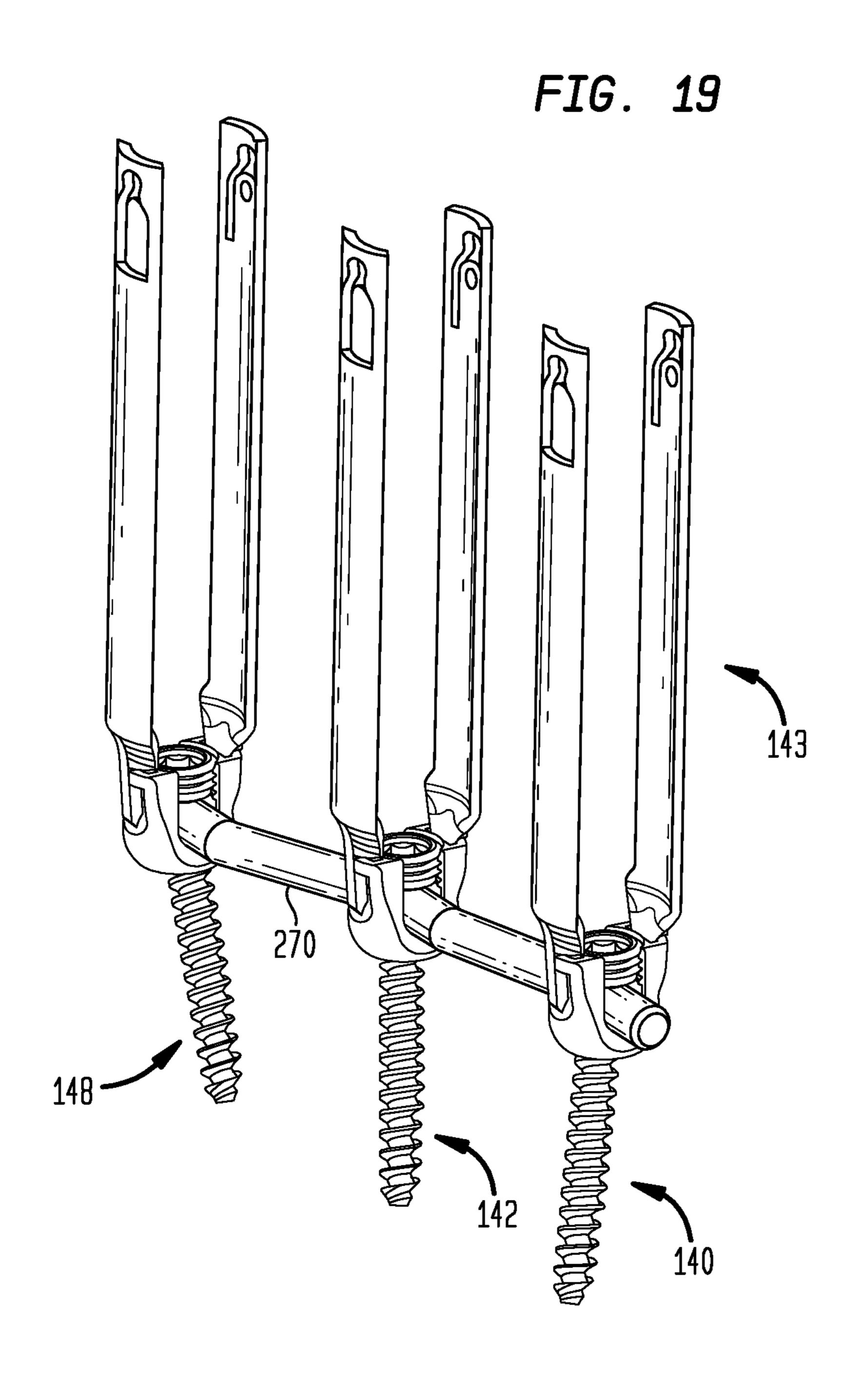


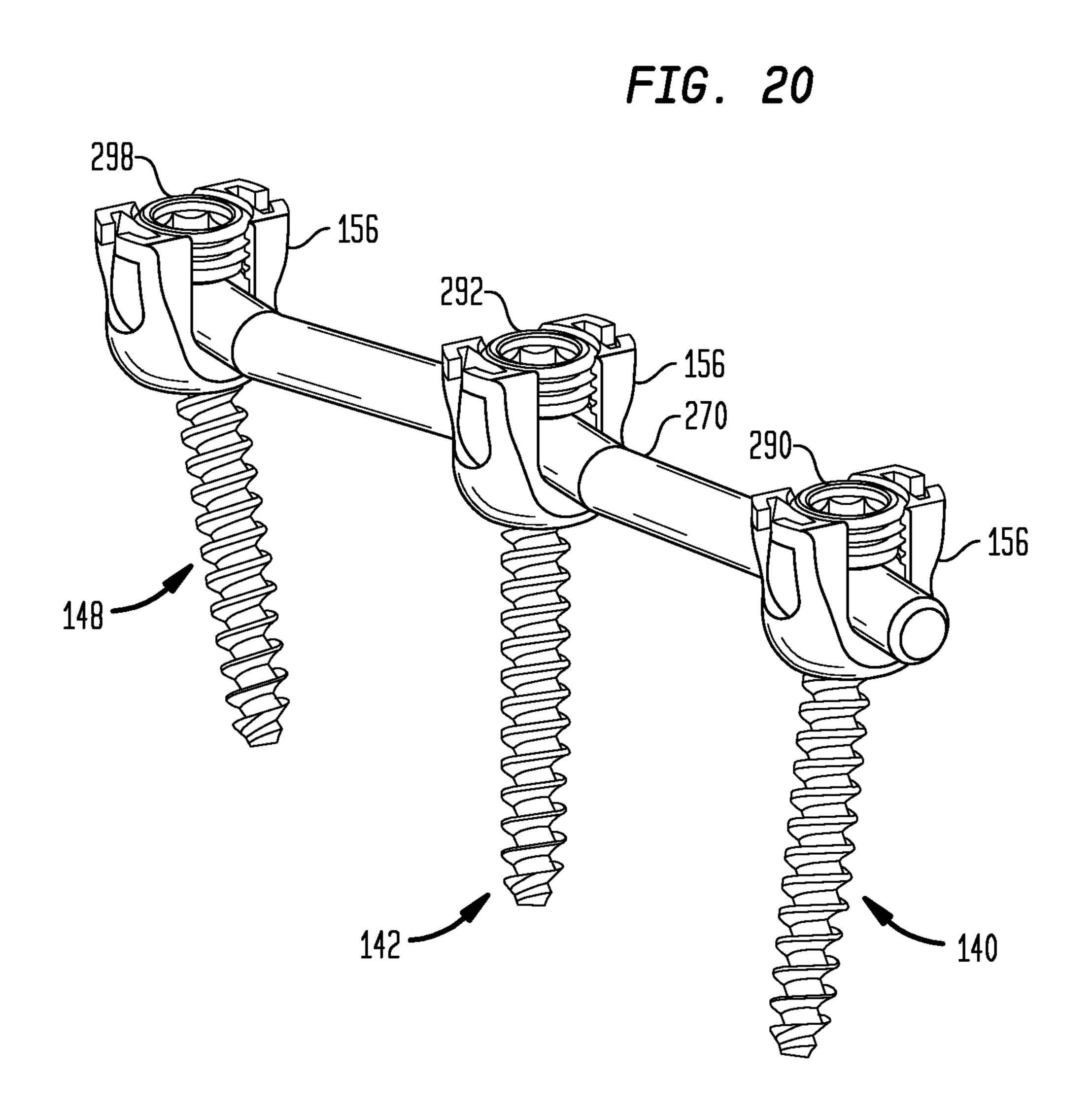












ROD CONTOURING APPARATUS FOR PERCUTANEOUS PEDICLE SCREW EXTENSION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 15/000,642, filed Jan. 19, 2016, which is a continuation of U.S. application Ser. No. 12/316,637, filed on Dec. 15, 10 2008, now U.S. Pat. No. 9,247,977, which is a divisional of U.S. application Ser. No. 11/526,785, filed on Sep. 25, 2006, now U.S. Pat. No. 8,894,655, and claims the benefit of the filing date of U.S. Provisional Application No. 60/765,606, filed Feb. 6, 2006, the disclosures of which are hereby 15 incorporated herein by reference.

This application relates to U.S. Application Ser. No. 10/868,075, entitled "Methods and Devices For Improving Percutaneous Access In Minimally Invasive Surgeries" and filed on Jun. 15, 2004, now U.S. Pat. No. 7,955,355; U.S. 20 application Ser. No. 11/178,035, entitled "System and Method For Orthopedic Implant Configuration" and filed on Jul. 8, 2005, now U.S. Pat. No. 8,177,817; U.S. application Ser. No. 11/202,487, entitled "System and Method For Spinal Implant Placement" and filed on Aug. 12, 2005, now U.S. Pat. No. 8,002,798; and International Application No. PCT/US2004/036640 and filed on Nov. 4, 2004, published as International Publication Number WO 2005/072081, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to methods and devices for improving percutaneous access in minimally invasive surgeries, and more particularly to methods and devices that 35 provide a template for the extracorporeal selection and contouring of connecting devices based on landmark locations within the body, and the percutaneous transfer of connecting devices and instruments, particularly such selected or contoured devices, within one or more access 40 channels to positions defined by particular locations within the body.

It is well known that traditional surgical procedures in locations deep within a patient's body require a long incision, extensive muscle stripping, prolonged retraction of 45 muscles for visualization, and denervation and devascularization of the adjacent tissue. These procedures result in extensive tissue traumatization and consequently in prolonged recovery time, risk of infections, high hospitalization costs, pain that can be more severe than the pain due to the 50 initial ailment, and in some cases permanent scarring. In minimally invasive surgical procedures, portals are used to access the locations deep in the patient's body. The use of portals rather than a long incision causes less trauma to the adjacent tissue, reduces the recovery time and pain and may 55 be performed in some case under only local anesthesia. The avoidance of general anesthesia reduces post-operative recovery time and the risk of complications.

Minimally invasive surgical procedures are especially desirable for spine surgeries because spine pathologies are 60 located deep within the body without clear muscle planes and there is danger of damaging the adjacent neural and vascular tissues. In treating the majority of spinal pathologies, the spinal muscles are stripped from the bony elements of the spine followed by laminectomy to expose the dura, the 65 nerve roots, and the discs. The incision has to be wide enough and the tissues have to be retracted to maintain a

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channel from the skin to the floor of the spinal canal that will allow direct visualization. This is similar to an open surgery approach to the knee to expose the menisci versus minimally invasive alternatives such as an arthroscopy which uses 1 centimeter portals under illuminated magnification which results in improved visualization, reduced postoperative knee pain, recovery time, and the destruction of healthy tissue. The destruction to the spinal structures is even more extensive during fusion procedures, which require more lateral tissue dissection and exposure to access the transverse processes and pedicles for placement of pedicle screws, rod constructs for stability, and bone graft under direct vision.

Furthermore, in spine fusion procedures, connecting elements, such as rods, plates or wires are placed and fixed between two or more locations of the spine. Placement of these connecting elements requires open surgery, which is currently one of the major limitations of other percutaneous cannula access methodologies. Accordingly there is a need for inserting and placing these connecting elements between two or more separate spinal locations without performing open surgery.

A wide variety of orthopedic implants exist. Such implants are typically anchored to bones within the body.

Every person has different bone structure; accordingly, implants must vary considerably in geometry to meet the needs of a broad range of patients. Connecting elements are an example of an orthopedic implant that often must be specially configured, adjusted, or selected based on the internal anatomical configuration of the patient's bone structure. Although visualization methods such as X-Rays and fluoroscopy can be utilized to help determine bone geometry, contact with the bones must often be made in order to provide a sufficiently accurate measurement of bony land-marks.

Trial fittings of an implant within the body are often required. In open treatment procedures, access to the operation site is typically sufficiently large to allow fitting and adjustment of implants such as connecting devices within the body. This is not feasible in minimally invasive surgical procedures because the surgeon has neither the physical access nor visibility required to test and adjust the device in situ.

According to new minimally invasive surgical (MIS) procedures, many orthopedic implants can be secured to bone through relatively small incisions. Unfortunately, if a larger incision must be made to permit bone measurement and implant selection or configuration, most of the beneficial effects of the MIS implantation procedure will be lost. Accordingly, there is a need in the art for bony landmark measurement and implant selection or configuration methods that can be carried out through small incisions. Such methods should be relatively simple and quick to perform, with comparatively simple instrumentation.

Furthermore, there is a need to provide a system, apparatus and method that solves the combined problems of using minimally invasive surgery for inserting and fastening implants such as connecting elements to bone locations such as spinal vertebrae and also allows configuration of the implants based on internal landmarks locations without performing open surgery.

SUMMARY OF THE INVENTION

In one aspect, the invention features apparatus for use as connectable portals in percutaneous minimally invasive surgery performed within a patient's body. The apparatus

includes a first elongated hollow tube having a proximal end and a distal end and defining a first working channel between the proximal end and the distal end when placed within the body cavity and a second working channel transverse to said first working channel comprising two slots along the length of the hollow tube.

In another aspect, the invention features at least a second elongated hollow tube having a proximal end and a distal end and defining a first working channel between the proximal end and the distal end when placed within the body 10 cavity and a second working channel transverse to said first working channel comprising two slots along the length of the hollow tube.

In another aspect of the invention the first and second tubes are sized for delivering carrier devices, surgical instruments, medical devices, fixation devices, vertebral disc replacement devices, interbody devices, fixation tools, connecting devices, connecting tools, tissue, grafting material, or illumination devices, to a pathology location within the body cavity through either the first or second working 20 channels. The surgical instruments may be scissors, scalpels, saws, drills, tissue dilators, biting and grabbing instruments, curettes, knot tying, or cautery. The fixation devices may be screws, hooks, loops, pins, nuts, washers, wires, sutures, or staples. The fixation tools may be screw drivers, pushers, 25 holders, wrenches, staplers, or knot tiers. The connecting devices may be plates, rods, wires, vertebral disc replacements, interbody fusion devices, or articulating versions thereof. The connecting tools may be connecting tools carriers, pushers, screw drivers, and wrenches. The illumi- 30 nation devices may be light sources, fiber optic cables, infrared detectors, magnification devices, and microscopes. The tubes may further comprise a mechanism for engaging and disengaging a fixation device. The tubes may further comprise separable components that can be assembled and 35 disassembled while at least partially within the body.

In an embodiment of the invention the first tube and second tube may comprise appendages at the distal end configured to releasably engage features of the fixation device and secure to the fixation device.

In an aspect of the method of the invention, the first tube comprises a first opening extending the entire width of the first tube and being located in a portion of the first tube within the first body cavity and wherein a cutting tool is used to incise tissue around the first body cavity through the first 45 opening. The method may also include inserting a second elongated hollow tube within a second body cavity of the patient adjacent to the first body cavity, wherein the second tube has a proximal end and a distal end and defining a second working channel between the proximal end and the 50 distal end when placed within the second body cavity. The method also includes incising tissue between the first body cavity and the second body cavity, thereby forming a path extending from the first body cavity to the second body cavity, then inserting a connecting device into or through the 55 first tube and then transferring the connecting device from the first tube to the second tube through the path. The method also includes attaching a first end of the connecting device to a first bone within the first body cavity via a first fixation device and attaching a second end of the connecting 60 device to a second bone within the second body cavity via a second fixation device. The first bone within the first body cavity may be a first vertebra, and the second bone within the second body cavity may be a second vertebra. The first and second fixation devices may be screws, hooks, loops, pins, 65 nuts, washers, wires, sutures, or staples and in a preferred embodiment is a multiaxial pedicle screw. The connecting

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device may be plates, rods, wires or articulating versions thereof and in a preferred embodiment is a rod. The tissue between the first and the second body cavities may be a lumbodorsal fascia and the path is located either above or below the lumbodorsal fascia. The first and second tubes are sized for delivering carrier devices, surgical instruments, fixation devices, fixation tools, connecting devices, connecting tools, tissue, grafting material, or illumination devices, to a pathology location within the body cavity. The method may also include inserting additional elongated tubes within additional body cavities of the patient adjacent to the first and second body cavities. The method may also include making a second incision on a second location of the patient's skin, then advancing a second guide wire through the second incision, through tissue underlying the second location and into a second underlying bone, then forming the second body cavity around the second guide wire and finally removing the first and second tubes from the first and second body cavities and closing the first and the second incisions.

The present invention has applications in a wide range of surgical procedures, and in particular in spinal procedures such as laminotomy, laminectomy, foramenotomy, facetectomy and discectomy, fusions or disc replacements using an anterior, posterior, postero-lateral, or a lateral approach to the disc space, facet, laminas, pedicles, or transverse processes. The devices and instruments of the present invention have application to surgical techniques that permit each of these several types of surgical procedures to be performed via a single or multiple sequential working channels. The present invention also has application to surgical techniques for preparing a disc space for insertion of an implant into the disc space.

In another aspect, the invention performs a function similar to a surgical navigation system with simple manual instruments that create a mechanical analog of the body target sites outside the body. This invention further provides a convenient template for the shaping of an implantable device to mate with target body sites without requiring a full surgical exposure to access the target body sites. This invention also provides a suitable level of positional control of the template to allow the surgeon discretion in positioning the template and shaping the implantable device.

In a still further aspect the invention provides an apparatus and a method for creating an extracorporeal set of reference features that replicates the spatial positioning of a set of target sites located inside the body, outside of the body. The target sites are preferably anchor sites for an implantable fixation device, but could be preferred locations for delivering therapeutic agents or anatomic locations.

In one embodiment, the invention creates extracorporeal references of the preferred anchor sites within the body for a fixation member to attach to bone anchors applied to the spine. This is accomplished by attaching elongate members to each bone anchors. Typically the members are attached to a first portion of a bone anchor that articulates with respect to a second portion of the bone anchor that is anchored to the bone. In the case of the application of the invention to a spine surgery, the anchors can be a pedicle screw or a pedicle hook for example.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and description below. Other features, objects and advantages of the invention will be apparent from the following description of the preferred embodiments, the drawings and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with reference to the appended drawings. It is

appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope.

FIG. 1 is a perspective view of two adjacent vertebrae of a spine, with guide wires implanted in the pedicles of the ⁵ right side.

FIG. 2 is a perspective view of three guide wires in isolation, positioned as though implanted in the pedicles of the right sides of three adjacent vertebrae.

FIG. 3 is a perspective view of the guide wires of FIG. 2, with dilators advanced along the guide wires to dilate surrounding tissue.

FIG. 4 is a perspective view of the guide wires and dilators of FIG. 3, with cannulas positioned around the dilators.

FIG. 5 is a view as in FIG. 4 with the dilators removed. FIG. 6 is a perspective view of the guide wires and cannulas of FIG. 5, with pedicle screws implanted in a pedicle along a guide wire through the use of an insertion 20

tool.

FIGS. 7 and 7A are perspective views of guide wires, pedicle screws and an insertion tool as in FIG. 6, with retractor blades having distal ends engaged with the pedicle screws and retained in position by abutment members to form a slotted cannula.

FIG. 8 is a perspective view of the retractor blades, abutment members and pedicle screws of FIG. 7, with trough simulation members used to form assemblies for contouring a fixation member attached to the distal portion of the retractor blades.

FIG. 9 is a perspective view of the assemblies of FIG. 8, with links bridging between the trough simulation members to retain the assemblies in an axially parallel relationship.

FIG. 10 is a perspective view of the cannulas, pedicle screws, trough simulation members, and bridges of FIG. 9, with a fixation member in the form of a rod seated in troughs of the simulation members for contouring.

FIG. 11 shows the contoured rod being percutaneously 40 guided through the retractor blades toward the pedicle screws.

FIG. 12 is a perspective view of the contoured rod, seated in the pedicle screws and being fastened by bolts using a driving tool.

FIG. 13 is a perspective view as in FIG. 14 of the contoured rod fastened to the pedicle screws.

FIG. 14 is a perspective view as in FIG. 15 of the contoured rod fastened to the pedicle screws after removal of the retractor blades.

FIG. 15 is a perspective view as in FIG. 9 except that the trough simulation members are not used and the links engage the retractor blades to retain the assemblies in an axially parallel relationship.

FIG. 16 is a perspective view as in FIG. 10 showing that 55 the distal portion of the retractor blades may be used in place of the troughs for contouring the rod.

FIG. 17 is a perspective view of the assemblies as in FIG. 8, with extenders that replace the trough simulation members and pass through the slotted cannulas to provide a 60 contouring feature.

FIG. 18 is a perspective view of the cannulas, pedicle screws, extenders, and bridges of FIG. 17, with a fixation member in the form of a rod seated in troughs of the simulation members for contouring.

FIG. 19 is a perspective view as in FIG. 18 of the contoured rod fastened to the pedicle screws.

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FIG. 20 is a perspective view as in FIG. 19 of the contoured rod fastened to the pedicle screws after removal of the retractor blades.

DETAILED DESCRIPTION

In this application, an "anatomic point" is a location within the body. An anatomic point need not be located on any specific anatomic structure. When applied to anatomy, "proximal" refers to a position relatively closer to the center of the body, and "distal" refers to a position relatively further from the center of the body. However, when referred to a tool or similar implement, "proximal" refers to a portion relatively nearer the operator of the tool or similar implement, and "distal" refers to a portion relatively further from the operator.

The phrase "spatial transformation" refers to any mathematical procedure in which one or more coordinates can be transformed in a manner that permits the original coordinates to be determined based on the results of the transformation. Accordingly, a spatial transformation may involve any combination of translation and rotation of the original coordinates, as long as the transformation can be analytically reversed to permit the original coordinates to be obtained. A "translational spatial transformation" is a spatial transformation in which the original coordinates are all uniformly translated along the same vector.

The term "mate" refers to any type of connection in which cooperating features engage each other to restrict relative motion of the mating parts. The term "couple" is not limited to fixed attachment, but also includes sliding attachment and the like. The term "receive" does not require one item to completely capture another; rather, one item receives another if the first item engages the second item in a manner that restricts relative motion of the items. The term "substantially parallel" means that a range of adjustment is available for limited relative movement of the assemblies, as the surgeon requires, to position the assemblies and also encompasses normal mechanical tolerances and deflections that create variance from geometrically parallel assemblies.

Referring to FIG. 1, a perspective view illustrates a portion of a spine 10. FIG. 1 illustrates only the bony structures; accordingly, ligaments, cartilage, and other soft tissues are omitted for clarity. The spine 10 has a cephalad direction 12, a caudal direction 14, an anterior direction 16, a posterior direction 18, and a medial/lateral axis 20, all of which are oriented as shown by the arrows bearing the same reference numerals. In this application, "left" and "right" are used with reference to a posterior view, i.e., a view from behind the spine 10. "Medial" refers to a position or orientation toward a sagittal plane (i.e., plane of symmetry that separates left and right sides from each other) of the spine 10, and "lateral" refers to a position or orientation relatively further from the sagittal plane.

As shown, the portion of the spine 10 illustrated in FIG. 1 includes a first vertebra 24, which may be the L5 (Fifth Lumbar) vertebra of a patient, and a second vertebra 26, which may be the L4 (Fourth Lumbar) vertebra of the patient. The systems and methods may be applicable to any vertebra or vertebrae of the spine 10 and/or the sacrum (not shown). In this application, the term "vertebra" may be broadly interpreted to include the sacrum.

As shown, the first vertebra 24 has a body 28 with a generally disc-like shape and two pedicles 30 that extend posteriorly from the body 28. A posterior arch, or lamina 32, extends between the posterior ends of the pedicles 30 to couple the pedicles 30 together. The first vertebra 24 also has

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a pair of transverse processes 34 that extend laterally from the pedicles 30 generally along the medial/lateral axis 20, and a spinous process 36 that extends from the lamina 32 along the posterior direction 18.

Similarly, the second vertebra 26 has a body 48 from 5 which two pedicles 50 extend posteriorly. A posterior arch, or lamina 52, extends between the posterior ends of the pedicles 50 to couple the pedicles 50 together. The second vertebra 26 also has a pair of transverse processes 54, each of which extends from the corresponding pedicle 50 generally along the medial/lateral axis 20, and a spinous process 56 that extends from the lamina 52 along the posterior direction 18.

The vertebrae 24, 26 and/or the intervertebral disc (not shown) between them, may be damaged or diseased in some 15 manner that makes it desirable to secure the vertebrae 24, 26 together in a manner that prevents relative motion between them. Accordingly, posterior spinal fusion may be employed to secure the pedicles 30 and 50 together in a geometrical relationship that produces a fused spinal section with an 20 appropriate bio-mechanical function. In order to allow the surgeon to provide a proper geometrical relationship between vertebrae, multiaxial pedicle screws and contoured rods connecting the screws have become the gold standard for spinal fusion hardware. FIGS. 1 through 16 illustrate an apparatus and method of configuring and installing a posterior spinal fusion system. FIGS. 17 through 20 illustrate an alternate embodiment for contouring the fixation member.

As further illustrated in FIG. 1, a first guide wire 70 has been inserted into the right-side pedicle 30 of the first 30 vertebra 24, and a second guide wire 72 has been inserted into the right-side pedicle 50 of the second vertebra 26. The guide wires 70, 72 pass through the saddle points 42, 62, respectively, of the pedicles 30, 50. Each of the guide wires 70, 72 has a proximal end 74 and a distal end 76. As shown, 35 the proximal ends 74 are exposed, and the distal ends 76 are implanted in the pedicles 30, 50. The distal ends 76 may be implanted by methods known in the surgical arts.

Referring to FIG. 2, a perspective view illustrates the first and second guide wires 70, 72 of FIG. 1, with the vertebrae 40 24, 26 not shown for clarity. The vertebrae are not shown for clarity in the subsequent FIGS. 3-20 also. A third guide wire 78 is also shown. The third guide wire 78 is positioned adjacent to the first and second guide wires 70, 72 as though the third guide wire 78 were implanted in the right-hand 45 pedicle of a vertebra (not shown) directly superior to the second vertebra 26. Accordingly, the method of FIGS. 1 through 20 may be used to secure together vertebrae on multiple levels, not just two adjacent vertebrae.

Referring to FIG. 3, a perspective view illustrates the 50 guide wires 70, 72, 78, in conjunction with a first dilator 80, a second dilator 82, and a third dilator 88. Each of the dilators 80, 82, 88 has a proximal end 92 and a distal end 94. The proximal ends 92 may be shaped for gripping by hand, or for attachment to a handle or the like. The distal ends 94 55 are rounded to permit relatively gentle spreading of tissues surrounding the guide wires 70, 72, 78 by the dilators 80, 82, 88.

Each of the dilators **80**, **82**, **88** has a bore sized to receive the proximal end **74** of the corresponding guide wire **70**, **72**, 60 or **78**, so that the dilators **80**, **82**, **88** are able to slide along the guide wires **70**, **72**, **78** toward the distal ends **74**, thereby spreading the tissues away from the guide wires **70**, **72**, **78**. As an alternative to the guide wires **70**, **72**, **78** and the dilators **80**, **82**, **88**, a variety of other guiding devices and/or 65 dilation devices may be used within the scope of the present invention.

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Referring to FIG. 4, a perspective view illustrates the guide wires 70, 72, 78 and dilators 80, 82, 88, with the addition of a first cannula 100, a second cannula 102, and a third cannula 108. Each of the cannulas 143 has a proximal end 112, a distal end 114, with a bore passing between the proximal and distal ends 112, 114. Each proximal end 112 has a port 116 in communication with the bore, and a tab 118 that may facilitate manipulation or securement of the corresponding cannula 100, 102, or 108.

Each distal end 114 has a taper 122 that provides a reduction in the diameter of the cannula 100, 102, or 108 toward the distal end 114.

The cannulas 143 are inserted around the guide wires 70, 72, 78. The cannulas 143 may be placed by withdrawing dilators 80, 82, 88, inserting the cannulas 143 around the proximal ends 74 of the guide wires 70, 72, 78, inserting the distal ends 94 of the dilators 80, 82, 88 into the ports 116 of the proximal end 112 of the cannulas 143, and then advancing the dilators 80, 82, 88 along the guide wires 70, 72, 78 to urge the cannulas 143 toward the distal ends 76 of the guide wires 70, 72, 78, into the dilated tissue.

According to one alternative method, the dilators 80, 82, 88 are removed to permit placement of the cannulas 143, and are not re-inserted. According to other alternative embodiments, cannulas (not shown) may be modular, or may have dilatable distal ends that enable placement of the cannulas around the dilators 80, 82, 88, so that the dilators 80, 82, 88 need not be removed from the guide wires 70, 72, 78 until the cannulas are properly positioned. The present invention is not limited to use of cannulas like those of FIG. 4; rather, any of a variety of cannulas may be used.

Referring to FIG. 5, a perspective view illustrates the guide wires 70, 72, 78 and cannulas 143, after the dilators 80, 82, 88 have been removed.

FIG. 6 is a perspective view showing the addition of the first of three cannulated connection elements 140 installed through the cannula 100 and into the vertebra using an insertion tool 170.

The connection elements may be fixation members designed to anchor a rod to the first vertebra 24, the second vertebra 26, and the third vertebra (not shown in FIG. 6). More precisely, the connection elements may be pedicle screws 140, 142, and 148 implantable in vertebral pedicles, as shown in FIG. 7.

The pedicle screws 140, 142, 148 may be designed to provide poly-axial coupling to the associated pedicles. Each of the pedicle screws 140, 142, 148 has a cage 152 shaped to receive a rod and a screw 154 that passes through an aperture (not visible) of the cage 152 in such a manner that the screw 154 is able to extend from the cage 152 along a plurality of relative orientations. Thus, after the screw 154 has been implanted in a pedicle, the orientation of the cage 152 with respect to the screw 154 can still be altered. Each of the screws 154 has a lumen passing along the axis of the screw 154 so that the screws 154 can slide along the guide wires 70, 72, 78 for accurate implantation in the pedicles.

As seen in FIG. 8, each cage 152 has two arms 156 that extend generally away from the screw 154 and define a trough 158 through which a rod (not shown in FIG. 5) can pass. The closed end of the trough 158 is rounded in a manner that corresponds to the radius of the rod to be retained within the cage 152 to facilitate secure retention of the rod. The inward-facing surfaces of the arms 156 may be threaded to enable the arms 156 to receive a nut (shown in FIG. 14). Tightening of the nut then presses the rod against the head 154 (shown in FIG. 14) of the screw 154 to keep

the rod in place within the slot 158 and to lock the orientation of the screw 154 with respect to the cage 152.

The pedicle screws 140, 142, 148 represent only one of many types of connection elements that may be used in connection with the present invention. A variety of known 5 devices may be used to secure a rod to a plurality of vertebra to provide posterior fusion.

Upon implantation in the pedicles, the pedicle screws 140, 142, 148 are positioned such that a first anatomic point 164, a second anatomic point 166, and a third anatomic point 168 are within the troughs 158 of the cages 152 of the first pedicle screw 140, the second pedicle screw 142, and the third pedicle screw 148, respectively. Upon installation of the rod in the troughs, the axis of the rod is to pass through the anatomic points 164, 166, 168.

Referring back to FIG. 7, seen extending from the connecting element 140, is a slotted cannula 143 and an abutment member 145. The cannula 143 is used to maintain access to the connecting element 140 after it has been implanted in the pedicle in a manner that facilitates percu- 20 taneous placement of the rod and attachment of the rod to the connecting element 140. The abutment member 144 helps to hold the cannula 143 together and keep it secured to the connecting element 140 in a manner that will be described subsequently. Additional cannulas 143 can be attached to 25 pedicle screws 142 and 148.

Prior to the installation of the connecting element 140 shown in FIG. 6, the slotted cannula 143 is assembled to the connecting element 140 as visible in FIG. 7. Upon assembly, the cannula 143 will have a proximal end 191 and a distal 30 end 192. The cannula 143 may be dimensioned such that the proximal end 190 protrudes above the skin while the distal end 192 is securable to the cage 152 and is insertable through the skin along with the cage 152. The cannula 143 includes a first retractor blade 195 and a second retractor 35 blade 197, which may be substantially identical to each other. Each of the blades 195, 197 has a proximal end corresponding to the proximal end 191 of the cannula 143, and a distal end corresponding to the distal end 192 of the cannula 143.

The retractor blades are detachably attached to the first portion of the bone anchor as shown in FIGS. 7 and 7A. Each distal end **192** has a distal tab **202**, and each proximal end 191 has a proximal tab 204. Each distal tab 202 has a locking ridge 206 that protrudes generally outward, and 45 extends generally circumferentially. Each distal tab 202 is also elongated, with a thin cross section that permits bending toward and away from the axis (not shown) of the cannula. Each proximal tab 204 has bends 208 that cause proximal tab **204** to jut outward, while remaining generally parallel 50 with the remainder of the corresponding blade 195 or 197.

Each of the distal tabs **202** is insertable through the slot 174 of the adjacent arm 172 of the cage 152 when the corresponding blade 195 or 197 is tilted to position the proximal end inward relative to the distal end. Once the 55 screws 154. distal tabs 202 have passed through the slots 174, rotation of the blades 195 or 197 back to a position generally parallel to each other, and to the axis of the cage 152, causes the distal tabs 202 to engage the edge of the slots 174 such that the bends 208 in the tab 202 are unable to slide back through the 60 178 provide access to the lumen for cleaning. slots 174. Thus, the blades 195 and 197 are then in a locked configuration, and cannot be detached from the cage 152. When they are again moved to the unlocked configuration, i.e., tilted to a position with the proximal ends 191 inward, the retractor blades can be unlocked and detached.

As long as the blades 195, 197 remain generally parallel to each other, the distal end 192 of the cannula 143 remains **10**

secured to the cage 152. Thus, the distal tabs 202 form a docking element that removably secures the cannula 143 to the connecting element 140. The abutment member 145 serves to keep the blades 195, 197 parallel to each other to keep the cannula 143 in assembled form and to simultaneously keep the cannula 143 secured to the cage 152 by keeping the blades 195, 197 from rotating into the unlocked configuration. When the cannula 143 is secured to the cage 152, the cannula 143 is in its "docked configuration." When the cannula 143 is removed from the cage 152, the cannula 143 is in its "undocked configuration."

As shown, the abutment member 145 is generally discshaped with a central opening and an open side that provides access to the central opening. The abutment member 145 also has a pair of arcuate slots that extend around opposing portions of the central opening and are sized to surround the first and second blades 195, 197 and keep the blades generally parallel to each other, and perpendicular to the abutment member 145. Thus, the blades 195, 197 are unable to pivot to the unlocked configuration when the abutment member 145 is installed to create an assembly and the cannula 143 maintains a generally tubular shape.

After the blades 195, 197 have been inserted into the arcuate slots, the abutment member 145 may be positioned at any of a range of positions along the cannula **143**. Thus, upon implantation of the pedicle screw 140 in the corresponding pedicle, the abutment member 145 can be positioned abutting the outward-facing surface of the patient's skin through which the cannula **143** passes. The abutment member 144 helps to stabilize the cannula 143 with respect to the tissues it passes through.

Once assembled to the pedicle screw 140, the cannula 143 has slots 220 extending along its entire longitudinal length, along opposite sides of the cannula 143. The slots 220 extend to the cage 152, and are therefore contiguous with the recesses defined in the arms 172 of the cage 152. Upon installation of the cannula and pedicle screw assembly by using the cannula 100 and tool 170 as shown in FIG. 6, the slots 220 will extend along the entire subcutaneous length of 40 the cannula **143** as better seen in FIG. **8**. Therefore, the rod for connecting the pedicle screws 14, 142, 148 may be inserted percutaneously through the slots 220 along a direction transverse to the axis of the cannula 143, and may then be moved through the slots 220 along the anterior direction 16, directly into the trough of the cage 152.

The pedicle screws 140, 142, 148, with or without the assembled cannulas 143, may be installed in a variety of ways. According to one method, the dilators 80, 82, 88 are first removed. Then, each of the pedicle screws 140, 142, **148** is implanted through the use of an insertion tool **170**. The insertion tool 170 has a handle 172 designed to be gripped by a hand, a distal end extending from the handle 172 and engaging the head of each of the screws 154. Thus, torque applied to the handle can be transmitted to each of the

The stem 174 also has a lumen (not shown) sized to fit around each of the guide wires 70, 72, 78 so that the guide wires 70, 72, 78 can be used to guide implantation of the screws 154 through the use of the insertion tool 170. Slots

Each of the screws 140, 142, 148 is coupled to the insertion tool 170 by connecting the head 154 of the screws to the distal end 176 of the stem 174. The insertion tool 170 is then moved to insert the proximal end 74 of the corresponding guide wire 70, 72, 78 through the lumen of the screw 154 and into the lumen of the stem 174. The insertion tool 170 is used to insert the pedicle screw 140, 142, or 148

through the corresponding cannula 100, 102, or 108 until the screw 154 contacts the first pedicle 30, the second pedicle 50, or the third pedicle. Then, torque and axial pressure are applied to the tool 170 to embed the threads of the screw 154 into the bone. The same method may be used to implant all 5 three of the pedicle screws 140, 142, 148. After the pedicle screws 140, 142, 148 have been implanted, the guide wires 70, 72, 78 may be removed.

As previously discussed, the fixation member in the form of a rod for connecting the pedicle screws 140, 142, 148 10 must be configured in three dimensional space to match the geometrical targets 164, 166, 168, in order to allow the pedicle screws to constrain the vertebrae in the desired positions once they are fastened to the rods. This requires that the rod be contoured. For better precision in contouring 15 the fixation member, simulation members, such as the trough simulation members 180 with base 182, stem 184 and troughs 188 as shown in FIG. 8, may be attached to the proximal end 191 of the cannula 143 to better replicate the geometry of the geometrical targets 164, 166, 168. In 20 conjunction with the cannula 143, the trough simulation members 180 provide a translational spatial transformation of the troughs 158 of the pedicle screws to the troughs 188 in order to use the troughs 188 as an extracorporeal template to bend the rod. The rod will later be attached in the troughs 25 158 of the pedicle screws 140,142,148 attached to the vertebrae within the body of the patient, placing the central axis of the rod in the troughs 158 to match the geometrical targets 164, 166, 168 at each trough location.

As shown in FIG. 8, the particular attachment method 30 employed for the trough simulation members 180 attaches the member to each proximal cannula end 191 with a proximal tab 204 releasably engaged with a slot in the trough simulation member. As will be later described, the trough simulation members 180 are but one example of a simulation member and other arrangements that project the positional relationship of the troughs 158 outside the body to achieve a translational spatial transformation, such as rods or cannulas that locate on the troughs 158 directly rather than through a cannula 143 are within the scope of the inventions. 40 Regardless of the configuration of the simulation members, the members must be retained in an approximately parallel axial relationship, be of the same length, and maintain the same alignment of each set of troughs 158 and 188 when using the externally projected troughs 188 to gauge the 45 contouring of the rod in order to provide an accurate translational spatial transformation of the troughs 158 and consequently allow the axis of the contoured rod to correctly fit within the troughs 158 in the geometrical targets 164, 166, **168**.

Referring to FIG. 9, a perspective view illustrates the cannulas 143, pedicle screws 140, 142, 148, and the trough simulation members 180 of FIG. 8, with the addition of a first link or bridge 250 and a second link or bridge 252. The bridges 250, 252 are used to keep the trough simulation 55 members 180 substantially parallel to each other to constrain the spatial transformation of the anatomic points 164, 166, 168. The bridges 250, 252 are designed to constrain the trough simulation members 180 only to parallelism. Thus, the bridges 250, 252 do not limit relative translation or 60 relative axial rotation of the trough simulation members 180.

Each of the first and second bridges 250, 252 has a first slider 254 and a second slider 256. The first slider 254 of each of the bridges 250, 252 has a pair of grooves 258 that face inward. The second slider 256 of each of the bridges 65 250, 252 has a pair of flanges that extend outward into the grooves 258 of the corresponding first slider 254 so that the

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first and second sliders 254, 256 are linearly slidable relative to each other to permit lengthening or shortening of the bridges 250, 252. Each of the sliders 254, 256 also has an aperture 262 that fits around the stem 184 of the corresponding trough simulation members 180. The apertures 262 are sized to fit around the stems 184 with relatively little clearance so that the bridges 250, 252 keep the trough simulation members 180 and thus the attached cannulas 143 and cages 152 parallel to each other without restricting relative axial rotation between the stems 184 and the apertures 162.

The bridges 250, 252 embody only one of many possible configurations that may be used in connection with the invention. According to one alternative embodiment (not shown), each bridge does not have two sliders, but has two members that are rotatably coupled to each other. Each of the members has an aperture like the apertures 262 of the bridges 250, 252, so that the bridges can permit relatively free relative translation and axial rotation of the trough simulation members 180 parallel to each other. The bridges would simply elongate and contract through the use of rotary motion instead of linear motion.

Returning to the configuration of FIG. 9, once the bridges 250, 252 have been applied, the trough simulation members 180 axially are parallel. The projected points 214, 216, 218 then mimic the relative positioning of the anatomic points 164, 166, 168 within the body and each pair of real and simulation troughs corresponding to the anatomic and projected points is in the same relative orientation to achieve a translational spatial transformation. Thus, the trough simulation members 180, in conjunction with the cannulas 143 and cages 152, apply a translational spatial transformation to the anatomic points 164, 166, 168 to move them to a more accessible location without altering their positions relative to each other. Accordingly, a rod contoured such that its axis passes through the projected points 214, 216, 218 may be installed such that its axis passes through the anatomic points 164, 166, 168 to properly extend through the cages 152 of the pedicle screws 140, 142, 148. An aspect of the invention is that in order for the projected points 214, 216, 218 to accurately correspond with the relative positioning of the anatomic points 164, 166, 168 within the body, the various mechanical interfaces of the intervening components between the points, such as the trough simulation members 180, the cannulas 143 and the cages 152, must have mechanical interfaces with suitable tolerances, such as axial concentricity and fit, to provide the necessary accuracy.

Referring to FIG. 10, a perspective view illustrates the cannulas 143, the pedicle screws 140, 142, 148, the trough simulation members 180, and the bridges 250, 252 of FIG. 9, with a rod 270 seated in the trough 180 of the trough simulation members 180 for contouring.

Due to natural variations in spinal morphology, the troughs 158 of the pedicle screws 140, 142, 148 may not be arranged in a straight line. Thus, the simulation troughs 180 may not be arranged in a straight line. Consequently, the rod 270 may need to be bent into the proper shape, for example, through the use of tooling such as pliers, French benders, a vice, or the like, so that it will lie properly within simulation trough 180. The process of deforming the rod 270 to the required shape may be termed "contouring."

Contouring may be carried out by, first, placing the undeformed rod 270 in the troughs 180 to determine how the rod 270 should be deformed to lie properly within the troughs 180. Then, the rod 270 is deformed, and again

placed in the troughs 180 to check the fit. This process is repeated until the rod 270 is shaped to provide an optimal fit with the troughs 180.

In the alternative to contouring, the rod 270 may simply be selected from a kit or the like. For example, such a kit (not 5 shown) may include rods bent at a variety of angles. The troughs 180 could be used to select the proper rod from the kit by placing each rod, in turn, on the troughs 180 until one is identified that has the proper fit. As another alternative, the rod 270 may be custom fabricated, for example, by mea- 10 suring the relative positions of the troughs 180 and using a CNC procedure to form the rod 270.

After the rod 270 has been configured or selected, the rod 270 and the trough simulation members 180 may be removed from the operating site as shown in FIG. 11, 15 leaving the pedicle screws 140, 142, 148 in place. The cannulas 143 may also be removed at this stage, depending on the method that will be used to implant the rod 270. The rod 270 may be inserted subcutaneously and placed on the cages 152 by making additional incisions to connect the 20 access passageways provided by the cannulas 143. Alternatively, MIS (Minimally Invasive Surgical) techniques, as subsequently described, may be used to implant the rod 270 without making additional major incisions, for example, by inserting the rod 270 subcutaneously and subfascially 25 through the slots 220 of the cannulas 143 using a rod holding tool 302.

As shown in FIGS. 12, 13 and 14, the rod 270 has now been seated in the troughs 158 of the cages 152 such that its axis passes through the anatomic points 164, 166, 168. The 30 use of a persuasion tool to seat a rod in a pedicle screw trough is well known in the art. Nuts 290, 292, 298 have been rotated into engagement with the inward-facing surfaces of the arms 156 of the cages 152 of the first, second, and third pedicle screws 140, 142, 148, respectively. The 35 nuts 290, 292, 298 have been tightened with a tool 304 to press the rod 270 against the heads of the heads 154 of the pedicle screws 140, 142, 148, respectively. Thus, the cages 152 are no longer freely rotatable with respect to the screws 154, but are instead locked in their current orientations.

The pedicle screws 140, 142, 148 thus cooperate with the rod 270 to restrict relative motion of the vertebrae to form a posterior vertebral fusion system. If desired, a similar system may be implanted in the left-side pedicles through the method set forth previously to provide a bilateral system. 45 Additionally, the present invention is not limited to a three-level fusion system, but may be used to fuse any number of vertebrae together. To fuse more than three vertebrae together, the steps set forth above may simply be repeated for each additional vertebra, and the rod may be placed on 50 four or more rod interfaces for configuration or selection.

The foregoing is only one of many methods encompassed within the scope of the present invention. According to one alternative method, the trough simulation members 180 may be omitted entirely from the procedure. Such a method may 55 commence with the steps outlined above in the descriptions of FIGS. 1 through 7, but may then include the steps illustrated in FIGS. 15 and 16.

Referring to FIGS. 15 and 16, a perspective view illustrates that in this embodiment the apertures 262 of the 60 bridges 250, 252 are sized to fit in close sliding contact with the outer surfaces of the cannulas 143 in order to keep the cannulas parallel to each other. The rod 270 is then manually positioned at the proximal end 191 of the cannula 170 and visually evaluated to conduct the contouring or selection 65 process described in conjunction with FIG. 10. While not providing the accuracy of an embodiment using simulation

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members, this method may be used to shorten the time necessary for the contouring step or be may be used to contour a trial rod or may be used for an initial contouring of a rod before using a simulation member.

FIGS. 17 through 20 depict an embodiment that uses a different type of simulation member than the trough simulation members 180 discussed above. As seen in FIG. 17 trough simulation rods 380 project the positional relationship of the troughs 158 outside the body, by passing through cannulas 143 and locating directly on the troughs 158. The trough simulation rod 380 has a trough interface 382, an elongate shaft 384 and simulation troughs 388 located at the proximal end of the rod. The trough interface 382 is configured to locate on the troughs 158 of the pedicle screws 140,142,148 attached to the vertebrae within the body of the patient, in order to determine the position of the geometrical targets 164, 166, 168 for the central axis of the rod 270. The shaft 384 projects the location of the troughs 158 to simulation troughs 388 external to the body and maintains a close concentric fit with the cannula 143 to ensure an accurate projection. Thus, similar to the previous embodiment using the trough simulation members 180, the trough simulation rods 380 provide a spatial transformation of the troughs 158 of the pedicle screws to the simulation troughs 388 in order to use the troughs 388 as an extracorporeal template to bend the rod. As in the previous embodiment, the trough simulation rods 380 must be retained in an approximately parallel axial relationship by structures such as bridges 250, 252, be of the same length, and maintain the same alignment of each set of troughs 158 and 388 when using the externally projected troughs 388 to gauge the contouring of the rod in order to provide an accurate projection of the troughs 158 and consequently allow the axis of the contoured rod to correctly fit with the troughs 158 in the geometrical targets 164, 166, 168 as previously described. The rod 270 will later be placed in the body and be attached to the pedicle screws as previously described in connection with FIGS. 11-14 and pictured in FIGS. 18-20. In the latter series of figures, a three 40 dimensionally contoured rod **270** is depicted.

A typical surgical procedure in accordance with the present invention will now be described. It will be understood by those of ordinary skill in the art that additional or fewer steps may be performed, the sequence of steps can be varied as appropriate and that substitute techniques and methods may be utilized. Nonetheless, during a typical surgery, a surgeon may perform the following steps:

percutaneously installing guide wires in bones, such as adjacent vertebrae, as shown in FIG. 1,

using blunt dilators and cannulas to open incisions and cavities as shown in FIGS. 2-5,

percutaneously installing polyaxial screws with retractor blades attached as shown in FIGS. 6,

removing the cannulas and guide wires as shown in FIGS. 7 and 7A,

installing the abutment members to form slotted cannula assemblies,

installing the trough simulation members or rods to the cannula assembly and/or the polyaxial screw head to form contouring assemblies as shown in FIG. 8 and alternatively, in FIG. 17,

aligning the contouring assemblies in a parallel relationship and installing the links onto the assemblies as shown in FIG. 9 and, alternately, in FIG. 17,

contouring the fixation member to fit the trough simulation members as shown in FIG. 10 or alternatively to fit into the trough simulation rods shown in FIG. 18,

installing the contoured fixation member percutaneously as shown in FIG. 11,

fastening the fixation member in the polyaxial screws as shown in FIGS. 12, 13 and 19, and

removing the elongate members as shown in FIGS. 14 and 5 20 and thereafter completing the surgery.

The foregoing description discloses a number of different elements, any of which may be components of a system for configuring or selecting one or more implants for implantation in a body of a patient. Although the foregoing 10 examples relate to the assembly and implantation of a posterior spinal fusion system, the present invention may be applied to a wide variety of implants, within and outside the orthopedic area. The present invention has particular benefits when an implant is to be configured or selected for a 15 given patient, with reference to two or more anatomic points within the body.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended 25 claims.

The invention claimed is:

- 1. A system for configuring or selecting one or more implants and for implanting the implants proximate the 30 spine in the body of a patient, the system comprising:
 - a first extender having a distal portion and a proximal portion, the first extender being positionable in a first implanted position in which the distal portion of the first extender is positioned proximate a first anatomic 35 point within the body and the proximal portion of the first extender is positioned outside the body, the first anatomic point being located proximate a first pedicle of a first vertebra of the spine;
 - a second extender having a distal portion and a proximal 40 portion, the second extender being positionable in a second implanted position in which the distal portion of the second extender is positioned proximate a second anatomic point within the body and the proximal portion of the second extender is positioned outside the 45 body, the second anatomic point being located proximate a second pedicle of a second vertebra of the spine; and
 - a first passageway device having a distal end and a proximal end and having a central longitudinal axis 50 extending therealong between the distal and proximal ends, the distal end of the first passageway device being configured to be positioned proximate the first anatomic point while the distal end is connected to a first pedicle fastener implantable in the first pedicle and 55 while the proximal end extends outside the body, the first passageway device defining a first passageway adapted to receive the first extender therein in a close concentric fit, the first passageway device and the first extender having a mechanical interface to constrain the 60 orientation of the first extender, and the first passageway device defining a first slot and a second slot extending along the central axis from the distal end to the proximal end, the first and second slots of the first passageway device being arranged to permit passage of 65 the one or more implants therethrough along a direction transverse to the central axis;

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- wherein the proximal portion of each of the first and second extenders includes a respective rod interface defining respective first and second projected points outside the body, the rod interfaces being shaped to receive a rod in a position extending simultaneously through the first and second projected points when the first and second extenders are positioned in the respective first and second implanted positions.
- 2. The system of claim 1, further comprising the first pedicle fastener, wherein the distal end of the first passageway device has a docking element discrete from and securable to the first pedicle fastener.
- 3. The system of claim 2, wherein the first pedicle fastener includes a pedicle screw having a cage connected thereto, the cage being configured to receive at least a portion of the one or more implants, and wherein the docking element comprises a plurality of tabs receivable in corresponding slots of the cage of the first pedicle fastener.
- 4. The system of claim 1, further comprising the first pedicle fastener, wherein the distal end of the first passageway device is connected to the first pedicle fastener by a frangible portion configured to fracture so as to permit the first passageway device to be removed from the first pedicle fastener.
- 5. The system of claim 4, wherein the frangible portion comprises a necked-down region designed to fracture in response to application of a certain pre-established linear force or angular moment.
- 6. The system of claim 4, wherein the first pedicle fastener includes a pedicle screw having a cage connected thereto, the cage being configured to receive at least a portion of the one or more implants, and wherein the first passageway device is formed as a single piece with the cage of the first pedicle fastener.
- 7. The system of claim 1, wherein the first passageway device comprises:
 - a first blade; and
 - a second blade discrete from the first blade;
 - wherein the first and second blades are positionable substantially parallel to each other to provide the first passageway device.
- 8. The system of claim 7, further comprising an abutment member encircling at least a portion of the first passageway device to abut an exterior skin surface of the patient, wherein the abutment member is movable along the first passageway device to define a variable subcutaneous length of the first passageway device, and wherein the abutment member is configured to restrict relative motion between the first and second blades.
- 9. The system of claim 1, further comprising an abutment member encircling at least a portion of the first passageway device to abut an exterior skin surface of the patient, wherein the abutment member is movable along the first passageway device to define a variable subcutaneous length of the passageway device.
- 10. The system of claim 1, further comprising a second passageway device having a distal end and a proximal end and having a central longitudinal axis extending therealong between the distal and proximal ends, the distal end of the second passageway device being configured to be positioned proximate the second anatomic point while the distal end is connected to a second pedicle fastener implantable in the second pedicle and while the proximal end extends outside the body, the second passageway device defining a second passageway adapted to receive the second extender therein in a close concentric fit, and the second passageway device defining a first slot and a second slot extending along the

central axis from the distal end to the proximal end, the first and second slots of the second passageway device being arranged to permit passage of the one or more implants therethrough along a direction transverse to the central axis of the second passageway device.

- 11. The system of claim 10, further comprising:
- a third extender having a distal portion and a proximal portion, the third extender being positionable in a third implanted position in which the distal portion of the third extender is positioned proximate a third anatomic point within the body and the proximal portion of the third extender is positioned outside the body, the third anatomic point being located proximate a third pedicle of a third vertebra of the spine; and
- a third passageway device having a distal end and a 15 proximal end and having a central longitudinal axis extending therealong between the distal and proximal ends, the distal end of the third passageway device being configured to be positioned proximate the third anatomic point while the distal end is connected to a 20 third pedicle fastener implantable in the third pedicle and while the proximal end extends outside the body, the third passageway device defining a third passageway adapted to receive the third extender therein in a close concentric fit, and the third passageway device ²⁵ defining a first slot and a second slot extending along the central axis from the distal end to the proximal end, the first and second slots of the third passageway device being arranged to permit passage of the one or more implants therethrough along a direction transverse to ³⁰ the central axis of the third passageway device;
- wherein the proximal portion of the third extender provides a respective third projected point outside the body when the third extender is positioned in the third implanted position, such that the one or more implants can be configured or selected based on locations of the first, second, and third projected points.
- 12. The system of claim 1, wherein the distal portion of the first extender is shaped to mate with an implant interface of the first pedicle fastener, and wherein the distal portion of the second extender is shaped to mate with an implant interface of a second pedicle fastener implantable in the second pedicle.

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- 13. The system of claim 1, further comprising a first bridge configured to constrain an orientation of the first extender with respect to the second extender to provide a spatial transformation of the first and second anatomic points to the first and second projected points.
- 14. The system of claim 13, wherein the first bridge is configured to keep the first and second extenders parallel to each other.
- 15. The system of claim 14, wherein the first bridge comprises:
 - a first slider configured to be coupled to a shaft of the first extender such that the first slider extends substantially perpendicular to the shaft and is rotatable about and slidable along the shaft; and
 - a second slider configured to be coupled to a shaft of the second extender such that the second slider extends substantially perpendicular to the shaft and is rotatable about and slidable along the shaft;
 - wherein the first and second sliders are configured to be slidably coupled together.
 - 16. The system of claim 13, further comprising:
 - a third extender having a distal portion and a proximal portion, the third extender being positionable in a third implanted position in which the distal portion of the third extender is positioned proximate a third anatomic point within the body and the proximal portion of the third extender is positioned outside the body, the third anatomic point being located proximate a third pedicle of a third vertebra of the spine; and
 - a second bridge configured to constrain an orientation of the second extender with respect to the third extender such that the system provides a spatial transformation of the first, second, and third anatomic points to first, second, and third projected points.
- 17. The system of claim 1, wherein each rod interface comprises a trough having a concave closed end and an opposing open end, and wherein, when the first and second extenders are positioned in the respective first and second implanted positions, the closed ends of the troughs are positioned distally of their open ends so as to receive the rod in the position extending simultaneously through the first and second projected points.

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